



WED-9618

Full Digital Ultrasonic Diagnostic System

# **Operation/Technical Manual**

(Version: V1.2, PN NO.: WED-20-11060911E)


**SHENZHEN WELL.D MEDICAL ELECTRONICS CO. LTD.**

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# Preface

## Statement

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- Information in this document is not annotated to change. The manufacture shall not state nor observe any warranty basing on this point, and definitely give up any implied warranty basing on any special purpose of selling or making benefit.
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-  is trade marks of Shenzhen Well.D Medical Electronics Co., Ltd. Any abuse of these trade marks without permission will be sued to assume legal responsibility according to laws.

## Manufacturer's warranty

- Shenzhen Well.D Medical Electronics Co., Ltd. assumes the responsibility for equipment security, reliability and performance only under the preconditions that the disassembly, assembly and maintenance of the equipment are all performed by its assigned professional and the equipment is used strictly in compliance with the operation manual.
- Shenzhen Well.D Medical Electronics Co., Ltd. ensures a guarantee period within a year and a half since the delivery day and promises there is no problem with the new equipment in material and technology. Within the guarantee period, Shenzhen Well.D Medical Electronics Co., Ltd. will maintain the equipment and replace the parts of non-man-made damages free of charge. But will not repair or replace the equipment surface if it is damaged.
- This guarantee is only available for failures occurred when the equipment is operated in compliance with the operation manual. And the guaranteed equipment can only be used in the prescribed range given in manual.
- This guarantee excludes losses or damages caused by external reasons such as thunder struck, earthquake, theft, unsuitable use or abuse and refitting the equipment.
- Shenzhen Well.D Medical Electronics Co., Ltd. shall not be responsible for damages caused by other devices or arbitrary connection to other devices.








- Shenzhen Well.D Medical Electronics Co., Ltd. shall not be responsible for losses, damages or injuries caused by delayed service request.
- When there is problem with the products, please contact Shenzhen Well.D Medical Electronics Co., Ltd. and explain the equipment model, serial number, date of purchase and the problem.

## Matters need Attention

- To ensure operational safety and long-term stable equipment performance, please read this operation manual closely and understand the equipment functions, operation and maintenance at all points before operating the equipment, especially contents of "Warning", "Caution" and "Note".
- Maloperation or inobservance of the instructions given by manufacturer or its agents may result in equipment damage or personal injury.
- The following convention works through this manual to lay special emphasis on some information.
  - ◆ "Warning": Stands for neglect of it will cause severe personal injury, death or realized property loss.
  - ◆ "Caution": Stands for neglect of it will cause slight personal injury or property damage.
  - ◆ "Note": to remind user of installation, operation or maintenance information. These information is very significant but with no risk. Any warning against dangers shall not be contained in NOTE.

## Safety labels

### Equipment labels explanation:

	Type B equipment
	Note! Refer to accompanying documents
	Turn-on (general supply)
	Disconnect (general supply)
	VIDEO
	Equipotential
	Risky voltage
IPX7	Protection against dripping water



USB



RS-232

**Packing and transportation labels explanation:**

	Handle carefully
	Temperature limit
	Upward
	Piling layer limit
	Keep dry
	Protect against heat

**Safety classification**

**According to the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide:**

WED-9618 not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide;

**According to the mode of operation:**

Continuous operation;

**According to the degree of protection against harmful ingress of water as detailed in the current edition of IEC 529:**

Main unit is general equipment, the probe is enclosed equipment protected against the effects of immersion, IPX7.

**According to the type of protection against electric shock:**

Class I equipment energized from an external electrical power source equipment;

**According to the degree of protection against electric shock:**

Type B

**General tips for equipment operation**

◆ **In operation**

1. Heat radiation holes are strictly prohibited to be covered.

2. After closedown, do not switch on the equipment within 2 - 3 minutes.
3. On scanning, if any abnormal case is found, stop scanning immediately and shut down the equipment.
4. The patient is prohibited to touch any non-applied part of the equipment.
5. When operating, do not press the keyboard panel too much, otherwise the equipment might be damaged.

#### ◆ **After operation**

1. Power off the equipment.
2. Pull out the plug from power supply socket instead of pulling the cable.
3. Clean off the couplant on the probe with soft medical sterilized cotton ball.
4. Put the probe into the special case.

### **General Safety Message**

Safety of the operator and patients and reliability of the equipment are taken into consideration during designing and producing, the following safety precaution must be implemented:

1. The equipment shall be operated by qualified operating staff or under their instructions.
2. Do not open the equipment and change the parameters without permission. If necessary, please turn to for Shenzhen Well.D Medical Electronics Co., Ltd. or its authorized agent for service.
3. The equipment has already been regulated into its optimal performance. Do not adjust any preset control or switch unless operate as per instructions in the manual.
4. If there is equipment failure, please shut down the equipment at once and contact for Shenzhen Well.D Medical Electronics Co., Ltd. or their authorized agent.
5. If it is needed to connect the equipment with other company's' electronic or mechanical devices , please contact Shenzhen Well. D Medical Electronics Co., Ltd. before connection.
6. Equipment operation, storage and transportation environment

Environmental requirements on normal operation:

- a) Environment temperature range: 0℃~+40℃
- b) Relative humidity range: ≤80%
- c) Atmosphere pressure range: 70KPa~106KPa

Environment requirements on equipment storage and transportation:

- d) Environment temperature range: -40℃~+55℃

e) Relative humidity range: <80% (20℃)

7. Do not hit the fragile TFT-LCD display. If it cracks, deal carefully with it in case the liquid crystal gets into eyes or mouths.
8. Must not hit the inner chargeable Li-ion battery nor throw it into fire in case it trigger an explosion ; Do not short circuit the battery output electrodes in case the battery be damaged; and please use the original binding charger to charge the battery. More over, because used battery will cause environment pollution, please handle the battery correctly for recovery processing.
9. Must not disassemble the power supply adapter. If failures happen, it should be handled by the professional; the charging output can only be used for charging the battery of the equipment, any improper use on other battery may cause explosion, fire and other unexpected hazards.
10. Must not short circuit the output of the adapter , a long term short circuit shall result in adapter damage.
11. Please use standard power cord as the input line of the network power supply for the adapter to reduce risk.
12. Shenzhen Well.D Medical Electronics Co., Ltd. shall not take any responsibility for any risk resulted from unauthorized re-fitment by the users.
13. To disconnect the equipment from the power supply network by unplug the adapter from the power supply network.
14. Refer to appendix A for sound output parameters.



**EMC statement:**

**WED – 9618 shall not affect the basic performance of radio service and other equipments and can work well in its stated electromagnetic environment.**

**Guidance and manufacturer's declaration – electromagnetic emission –  
for all EQUIPMENT AND SYSTEMS**


Row

1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The WED-9618 Full Digital Ultrasonic Diagnostic System is intended for use in the electromagnetic environment specified below. The customer or the user of the WED-9618 Full Digital Ultrasonic Diagnostic System should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The WED-9618 Full Digital Ultrasonic Diagnostic System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

**Guidance and manufacturer's declaration – electromagnetic immunity –  
for all EQUIPMENT and SYSTEMS**

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The WED-9618 Full Digital Ultrasonic Diagnostic System is intended for use in the electromagnetic environment specified below. The customer or the user of the WED-9618 Full Digital Ultrasonic Diagnostic System should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 6$ kV contact $\pm 8$ kV air	$\pm 6$ kV contact $\pm 8$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1$ kV differential mode $\pm 2$ kV common mode	$\pm 1$ kV differential mode $\pm 2$ kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle  $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycles  $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycles  $< 5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 sec	$< 5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle  $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycles  $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycles  $< 5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WED-9618 Full Digital Ultrasonic Diagnostic System requires continued operation during power mains interruptions, it is recommended that the WED-9618 Full Digital Ultrasonic Diagnostic System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a. c. mains voltage prior to application of the test level.			

**Guidance and manufacturer's declaration – electromagnetic immunity –  
for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING**

Guidance and manufacturer's declaration – electromagnetic immunity			
The WED-9618 Full Digital Ultrasonic Diagnostic System is intended for use in the electromagnetic environment specified below. The customer or the user of the WED-9618 Full Digital Ultrasonic Diagnostic System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	1 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the WED-9618 Full Digital Ultrasonic Diagnostic System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</p> <p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WED-9618 Full Digital Ultrasonic Diagnostic System is used exceeds the applicable RF compliance level above, The WED-9618 Full Digital Ultrasonic Diagnostic System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WED-9618 Full Digital Ultrasonic Diagnostic System.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			

**Recommended separation distances between portable and mobile  
RF communications equipment and the EQUIPMENT or SYSTEM -  
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

<b>Recommended separation distances between portable and mobile RF communications equipment and the WED-9618 Full Digital Ultrasonic Diagnostic System</b>			
The WED-9618 Full Digital Ultrasonic Diagnostic System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WED-9618 Full Digital Ultrasonic Diagnostic System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WED-9618 Full Digital Ultrasonic Diagnostic System as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output of transmitter  W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz  $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz  $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz  $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.1	0.38	0.73
1	3.5	1.2	2.3
10	11	3.8	7.3
100	35	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

## Contraindication

- ★ The equipment is not suitable for inspection on organs containing with gas such as lung, etc.
- ★ It is recommended not to check the parts with wounded or acute inflammation to avoid the cross infection.
- ★ Patient in the following situations are not allowed to be checked with vagina and rectum probes:

inflammation of the vagina , such as trichomonas virginitis, colpomycosis, venereal disease etc ; The unmarried, deformity of vagina, menstrual period, postmenopausal vagina atrophy, person with difficulty carry on the vagina ultrasonic examination, colporrhagia, placenta previa patient, etc.

★ The following patient is prohibited to use the puncture

High blood pressure, coronary heart disease, disturbance of blood coagulation and the bleeding tendency patient

#### **Warning**

**When WED-9618 works in strong electromagnetic environment exceeding its statement, its image might be interfered and the diagnoses could be influenced. At this time, please stop operating until the EMC interference is removed.**

#### **Warning**

**When WED-9618 works at the state of overlapping or paralleling with other equipments, there might be unexpected EMC problems ; If it must work close to other equipments, please observe carefully and check if some equipment is influenced by unexpected EM coupling.**

#### **Warning**

**Replacement of non-standard probe parts may cause unexpected EMC problem.**

#### **NOTE**

**Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC60601-1. IF in doubt, consult the technical service department or your local representative.**

# 1 Summary

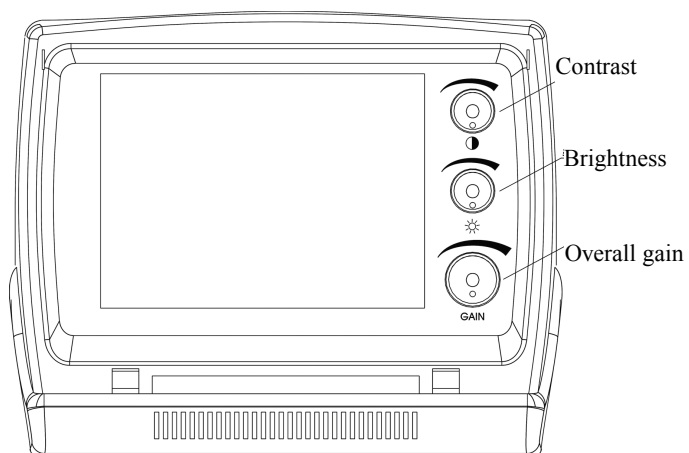
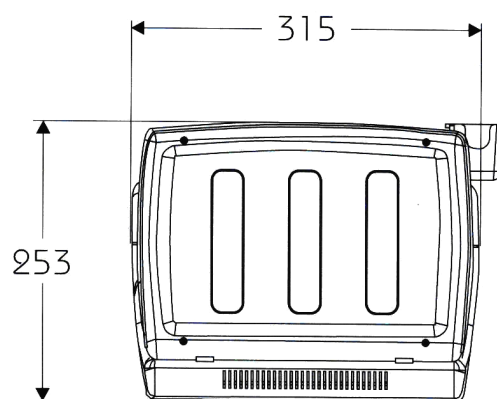
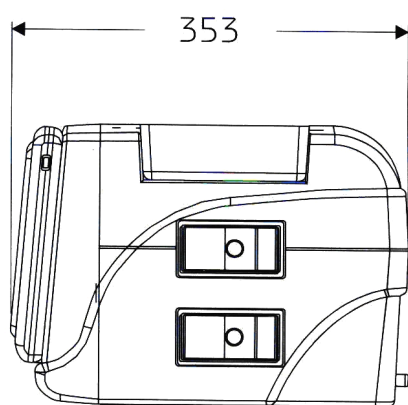
## 1.1 Brief Introduction

- This equipment is high resolution linear/convex ultrasound scanning diagnostic equipment. It adopts micro-computer control and digital scan converter (DSC), digital beam-forming (DBF), real time dynamic aperture (RDA), real time dynamic receiving apodization, real time Dynamic receiving focusing (DRF), Digital frequency Scan (DFS), 8 segments TGC, frame correlation technologies to endue its image with clarity, stability and high resolution.
- There are six display modes: B, B+B, B+M, B+M/M, M and 4B; And 256 gray scale.
- The system can process real time image display, freeze, save, load, zoom, up and down flip, left and right flip, black and white flip, and capacity cine loop; Multi-level scanning depth, angle, dynamic range, acoustic power, frame correlation factor regulation and focus number, focal space, focus position, etc. It offers more than 40 body marks.
- Date, clock display; Name, sex, age, doctor, hospital annotation; Distance, circumference, area, volume, heart rate measurement; preset two obstetric tables to measure GA, FW and EDD. Many probes are optional for clinic diagnosis demands.
- PAL-D video output offers connection to external video image printer and big display and other equipments. High speed USB port provides real time image transfer to the PC.
- Adoption of folded soft push keyboard and trackball provides immediate, convenient and flexible operation. The equipment is jet molding enclosure and potable structure, the usage of non-industrial frequency transformer switching power supply, programmable parts (FPGA) and surface mounting technology (SMT) make the whole unit highly compact.

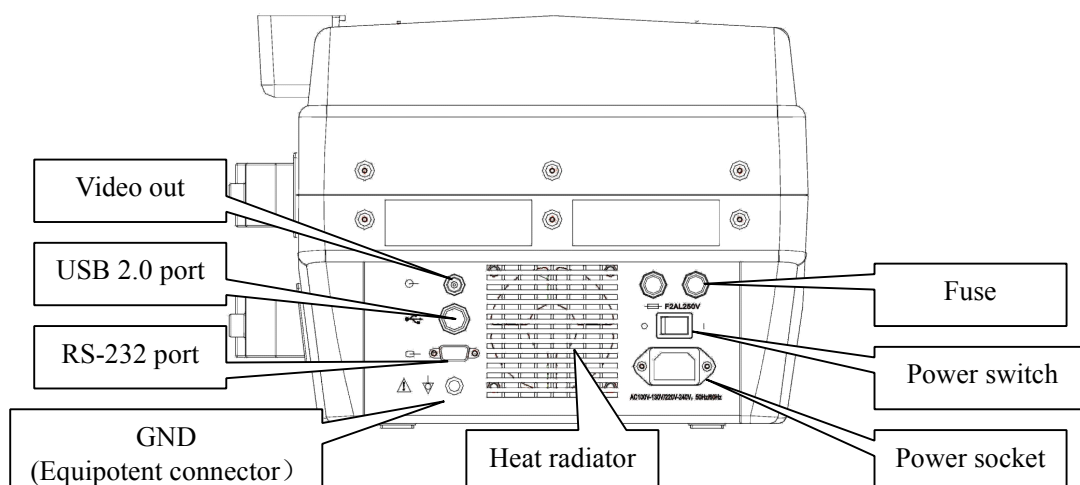
## 1.2 Range Of Application

Application in abdominal, Obstetric, Cardiac, small parts sonography.

### 1.3 Appearance



Front Panel



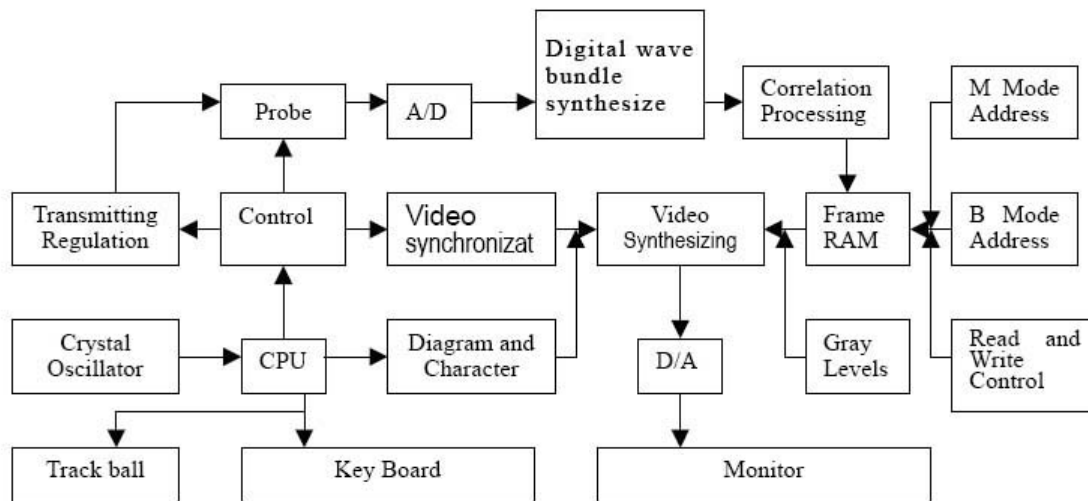
Rear Panel

## 1.4 Technical Specificatio

Probe		C1-7/60R/3.5MHz convex array	L1-3/7.5MHz HF linear	C1-8/20R/5.0MHz micro convex	EC1-2/13R/6.5MHz endo-vaginal
Display depth (mm)		250 (max)			
Maximal detect depth (mm)		$\geq 190$	$\geq 80$	$\geq 90$	$\geq 90$
Resolution (mm)	Lateral	$\leq 2$ (depth $\leq 80$ ) $\leq 3$ (80<depth $\leq 130$ )	$\leq 1$ (depth $\leq 60$ )	$\leq 1$ (depth $\leq 40$ )	$\leq 1$ (depth $\leq 40$ )
	Axial	$\leq 1$ (depth $\leq 80$ )	$\leq 0.5$ (depth $\leq 80$ )	$\leq 0.5$ (depth $\leq 40$ )	$\leq 0.5$ (depth $\leq 40$ )
Blind zone(mm)		$\leq 3$	$\leq 3$	$\leq 2$	$\leq 2$
Geometric position precision	Horizontal	$\leq 0$	$\leq 3$	$\leq 4$	$\leq 2$
	Vertical	$\leq 3$	$\leq 5$	$\leq 2$	$\leq 2$
Monitor size		10 Inch			
Display mode		B, B+B, B+M, B+M/M, M, 4B			
Image gray scale		256 Scale			
Cine loop		$\geq 500$ Frame			
Image storage		64 Frame			
Scan angle		Adjustable			
Scan depth		40mm-250mm			
Image flip		Up/down, left/right, black/ white			
Image Process		GAMA, Image Smoothen, THI, Histogram, Zoom			
Focus		Focus Number, Focus position, Focal space			
Measure		Distance, circumference, area, volume, heart, GA, FW, EDD			
Character display		Date, clock, name, PID, age, Sex, hospital name, doctor,			
Notation		full-screen character editor, posture mark, Position indication			
Output report		4 types			
USB port		USB2.0			
power consumption (MAX)		100VA			
Net weight		6.4kg			
Size		253mm $\times$ 315mm $\times$ 353mm			



## 1.5 Electric principle block diagram



## 1.6 Standard configurations

- ✓ Mainframe
- ✓ C1-7/60R/3.5MHz convex array
- ✓ PS cable
- ✓ 2 pieces of fuse tube F2AL250V
- ✓ Coupling gel 250ml
- ✓ User Manual
- ✓ Final examination report
- ✓ Packing List

## 1.7 Optional pieces

- ✓ C1-8/20R/5.0MHz Micro-convex probe
- ✓ L1-3/7.5MHz HF linear probe
- ✓ EC1-2/13R/6.5MHz Endo-vaginal probe
- ✓ High speed USB cable
- ✓ Monitor
- ✓ Video printer

### Warning:

**Please use the spare parts specified above. The manufacturer shall not bear the responsibility of safety problem, unexpected EMC performance drop caused by arbitrary adoption of non-specified spare parts.**

## 2 Installation

### 2.1 Operation environmental requirements

- Environment temperature range: 0℃ ~+40℃
- Relative humidity range: ≤80%
- Atmosphere pressure range: 70kPa~106kPa
- Power supply: a. c. 110V~130V/220V~240V, 50Hz/60Hz
- Avoid strenuous vibration during operation; Keep away from equipments with high electric field, high magnetic field and high voltage; avoid strong sunlight on the display; Keep the equipment well-ventilated, damp proof and dustproof.

#### **Note:**

**Check according to the "packing list" after uncasing and make sure that there is no shipping damage, and then install the equipment according to requirements and methods described in "Installation".**

#### **Warning:**

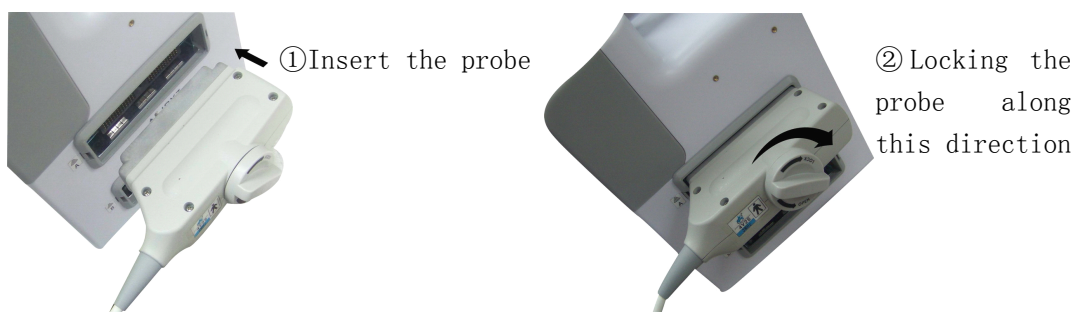
**If there is breakage at unpacking check, it is banned to use the device to ensure security.**

**The probe should be protected from felling off or crashing and the manufacturer.**

### 2.2 Connecting probe and main unit

Check the power supply too see if it is in the expected range (a.c.110V~130V/220V~240V, 50Hz/60Hz), then connect the equipment and the power socket with the cable.

Connect the probe:



### **Warning:**

**Do not by all means unplug or plug the probe connector at state of log on in case the probe and main unit be damaged.**

**Once the probe is connected with the main unit, do not unplug nor plug it at discretion in case poor contact happen.**

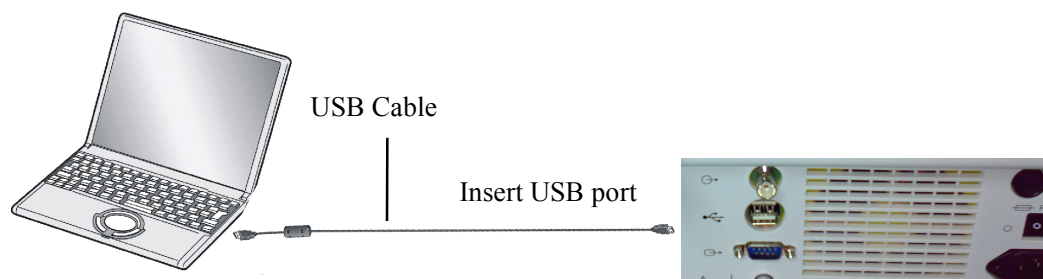
**The probe should be protected from falling off or crashing and the manufacturer assumes no responsibility for the kind of hazard.**

**Must not touch the contact pin in the probe connector.**

**Please handle the equipment carefully.**

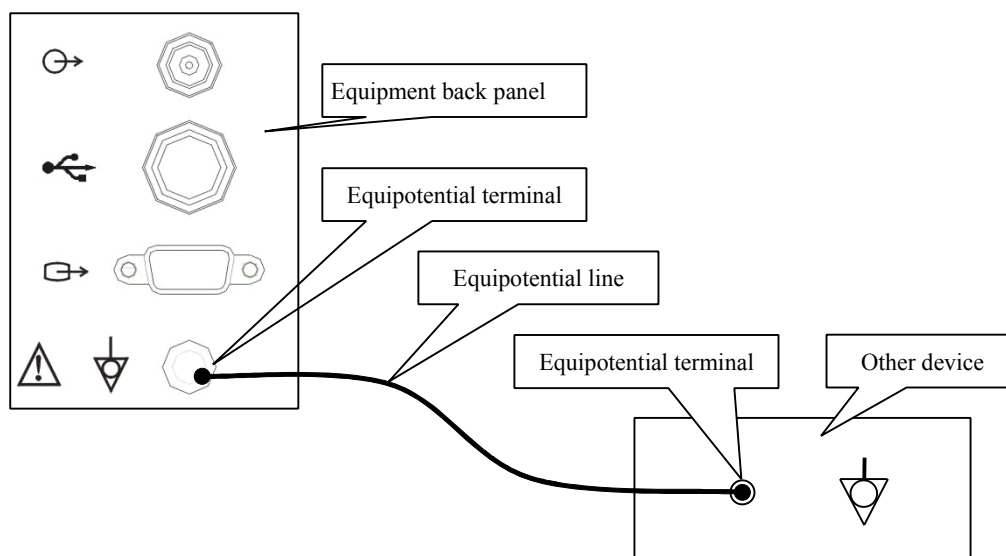
## **2.3 Image management software installation**

Installation steps, see the documentation in CD, you can see the help document to use.



## **2.4 Equipotential connection**

See the figure:



## **Warning**

**Equipotential: When this equipment is used together with other device, equipotential should be in consideration.**

**When the equipment is in use, the doctor and patient are under the risk of uncontrollable compensating current influence, which is caused by different electric potential between facilities and tangible current carrying parts. The most safe solution is set up a united equipotential network, and connect the medical equipments with the equipotential network in the treatment room.**

### 3 Operating procedures

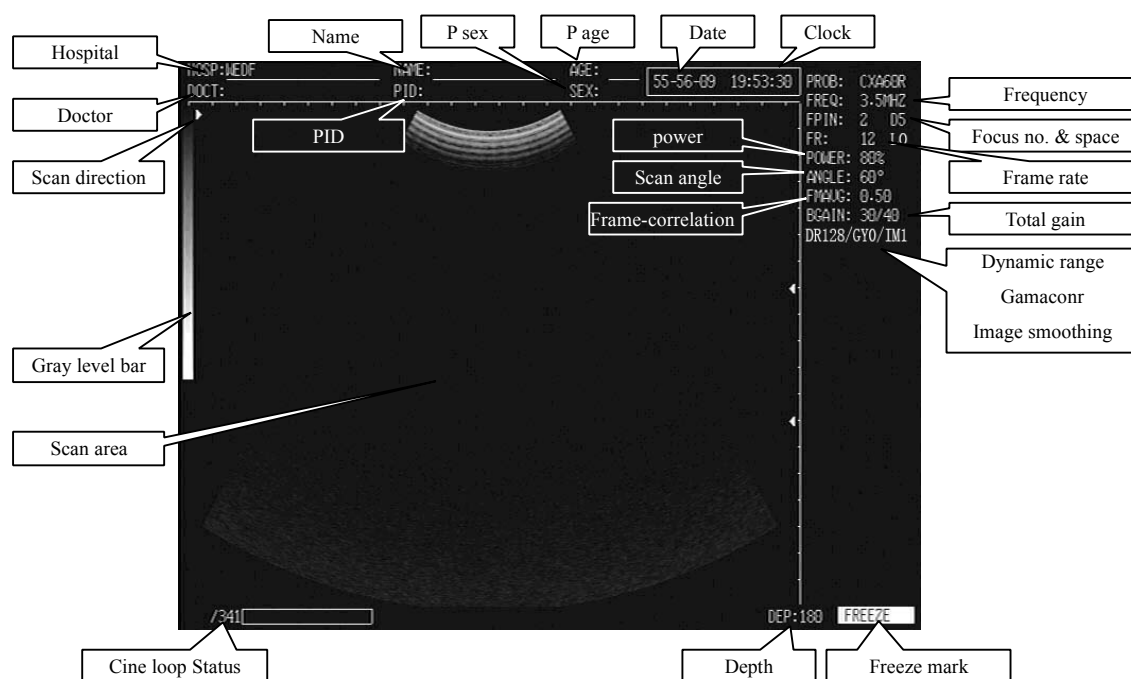
### 3.1 Introduction of keyboard



Number character includes below double function keys:

- |     |  |
|-----|--|
| “1” | Press this key to move cursor or sampling line left  |
| “2” | Press this key to move cursor up                     |
| “3” | Press this key to move cursor down                   |
| “4” | Press this key to move cursor or sampling line right |
| “0” | Control the cursor moving speed by direction keys    |

### 3.2 Display interface



### **3.3 Operating procedures**

1. Switch on the equipment.
2. Press any button to enter the B-type ultrasonic scan interface.
3. Type the basic information of the patient.

Press “Annotation” to type the information including name, PID, age, gender, hospital, doctor.

4. Spread ultrasonic coupling agent on the probe acoustic shadow surface, and close to the scanning area, then the real-time image can be observed on the screen.
5. Freeze the image, and conduct measurement on the image.
6. Create a report, print the report and image by the connected video printer.

## 4 Image parameter adjustment

### 4.1 Display mode switching

#### B mode switching

Press “**B**” button to switch current image to real-time single B mode. (The default mode when the equipment is power on)

#### BB mode switching

Press “**BB**” button to switch the current image to double B mode. Real-time image and freeze image are displayed on the screen. Press “**BB**” button continuously to switch the real-time and freeze states of two images.

#### B+M mode switching

Press “**BM/M**” button to switch the current image to B+M mode. B type and M type real-time images can be displayed on the screen at the same time. The sample line of B type image can be moved around by mouse and arrow button.

#### B+M/M mode switching

Press “**4B**” button to switch the current image to B+M/M mode in the B+M type or M type real-time scanning mode. B type and 2 M type real-time images can be displayed on the screen at the same time. The sample line of B type image can be moved around by mouse and arrow button. Press “**L/R**” button to Change the current sampling line.

#### M mode switching

Press “**BM/M**” button to switch the current image to M mode in the B+M type real-time scanning mode. And then an M type image is displayed on the screen.

#### 4B mode switching

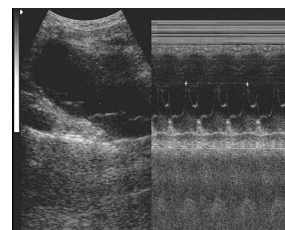
Press “**4B**” button to switch the current image to 4B mode in the B type, BB type real-time scanning mode. Four B type images are displayed, one of which is in a real-time state. Press “**4B**” button continuously to switch the real-time and freeze states of four images.



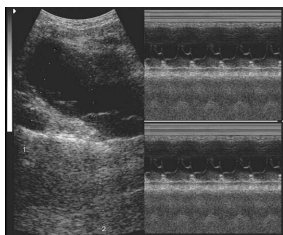
B



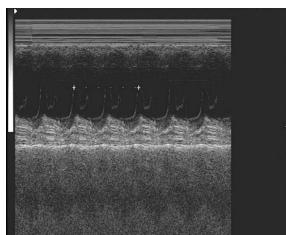
BB



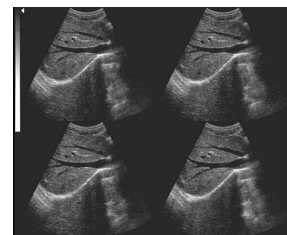
B+M



B+M/M



M



4B

#### Attention:

**When you call up the menu, please exit the menu before switching the display mode.**

## 4.2 Image freezing

Press “**Freeze**” button to switch real-time state and freeze state. “FREEZE” on the bottom of screen is the freeze mark.

## 4.3 Gain adjustment

Total gain control key. There are four steps: 25, 30, 35, 40. Press “**G**” key to set them circularly.

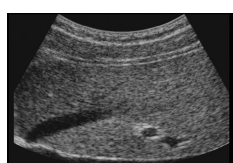
Regulate the gain knob to control gain, The gain setting range is 0-62

## 4.4 Depth adjustment

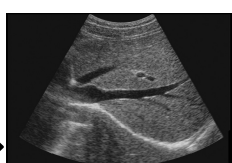
Press **Depth** ↑ or **Depth** ↓ key in the B BB BM type real-time mode to switch the current scanning depth.

The current depth is displayed on the bottom right of screen. The depth adjustment range changes with different probe type. The following table is presented as a reference.

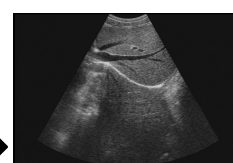
Probe type	C1-7/60R/3.5MHz	L1-3/7.5MHz	C1-8/20R/5.0MHz	EC1-2/13R/6.5MHz
depth(mm)	90~250	40~105	80~150	50~120



Depth 90



Depth 180



Depth 240

## 4.5 Scanning angle adjustment

Press “**Angle**” button in real-time state to active this function. The “Angle” on the right of screen is lightening. Then switch the scanning angle with ↑ ↓ key . When mentioning probe angle, please refer to the following table.

Press “**Cancel**” in turn to exit.



Probe type	C1-7/60R/3.5MHz	EC1-2/13R/6. 5MHz	C1-8/20R/5. 0MHz
angle	60° visual and adjustable	120° visual and adjustable	90° visual and adjustable

## 4.6 Dynamic range adjustment

Press “DR” button in real-time state to active this function. The “DR” on the right of screen is lightening. Then adjust the dynamic range with ↑ ↓ key. The dynamic range is 0-192dB, and the adjustment range is 64-192dB.

Press “**Cancel**” in turn to exit.

## 4.7 Focus adjustment

### Focus number

Press “FPin” key to lighten up the “FPIN” on the screen right top, press again to change the focus numbers.

There are two focus at most. Press this key to switch between one focus to two.

Press “**Cancel**” in turn to exit.

### Attention:

**When the focus is set to 2, the current image frame frequency would be reduced.**

### Focus space selection

When set the focus number as two, their distance can be adjusted. There are 5 levels focus space 2, 3, 4, 5, 6 and press “Span” key repeatedly to switch among them circularly.

### Focal position

Press “FPin” key to lighten up the “FPIN” on the screen right top, and then move the focus up and down with ↑ ↓ key, and change the focal position.

Press “**Cancel**” in turn to exit.

### Tip:

**The focusing of image near the focus indicator  is better, and you can change the focus number and focal position, so that the focus will point to the interest areas.**

## 4.8 probe work frequency

At real time estate, press “**Frequency**” key, change the working frequency of the probe. The frequency of each probe is given bellow:

C1-7/60R/3.5MHz —— 2.5MHz、3.5MHz、5.0MHz

C1-8/20R/5.0MHz —— 4.5MHz、5.0MHz、5.5MHz

EC1-2/13R/6.5MHz —— 5.5MHz、6.5MHz、7.5MHz

L1-3/7.5MHz — 6.5MHz、7.5MHz、8.5MHz

The current probe frequency displays on the up right of the screen.

## 4.9 Change probe

This equipment is fitted with two probe connectors (A, B). Press “**probe-S**” key to switch the probes. The current probe model appears on the right top of the screen.

### Tips:

**The device can automatically identify probes.**

**When it is connected with two probes. The system default working probe is the one connecting to socket A.**

**Please shut down the system first before replacing probes. Restart the system, it can realize automatic identification.**

## 4.10 Frame-related adjustment

Press “M Volocity Correlation” buttons in real-time B mode, BB, 4B mode states to active frame-related adjustment. “FMAVG” on the right of screen is lighting. Change the frame size with ↑ ↓ key, and the result will be displayed on the right of screen, such as “FMAVG: 0.55”. The adjustment range is 0.20-0.95.

Press “**Cancel**” in turn to exit.

### Tip:

**If the frame-related adjustment is conducted in the BM mode, “Frame Related” on the right of the screen should be lightened in B or BB mode before entering the adjustment mode.**

## 4.11 M rate adjustment

Press “M Volocity Correlation” button in real-time B+M, B+M/M, M mode to adjust the refresh rate of M-type image on the screen. The current scan rate is displayed on the bottom of screen, such as “ST=2.50S”. There are four levels listed as 3.00S, 2.50S, 2.00S, 1.25S to adjust in B+M mode, and four levels listed as 6.00S, 5.00S, 4.00S, 2.50S to adjust in M mode.

## 4.12 Power Adjustment

At real time or freeze, press “**D**” key adjust acoustic , Right of the screen shows “POWER: 80%” or “POWER: 100%”.

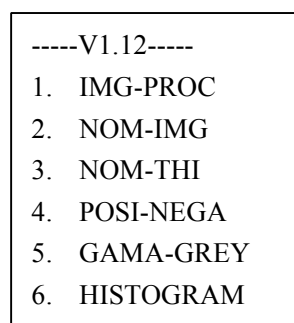
### Attention:

**Ultrasound may cause harm to human, Be sure to avoid prolonged exposure to high power, Use with caution.**

## 5 Image processing

### 5.1 Overview

Press “**Image Processing**” button to display the menu which including some image processing functions, then press the corresponding number to enter. The “V1.12” on the top of menu presents current software version number. Press “**Cancel**” button to exit the menu.



### 5.2 Image smoothing

Press “**Image Processing**” → “1” button in real-time state to active this function. The “IM” on the right of screen is lightening. Then adjust sharpen level with ↑ ↓ key, there are 4 levels can be chosen, which listed as IM0, IM1, IM2, IM3.



Common image

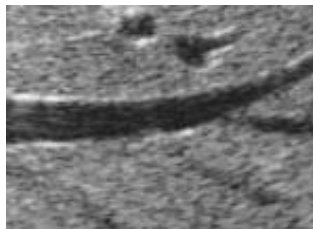


Image after smoothing

### 5.3 Tissue harmonic imaging

Press “Image Processing” → “3” button in real-time state to open the tissue harmonic imaging, “THI” on the bottom of screen is the tissue harmonic imaging mark.

Close tissue harmonic imaging, Press “Image Processing” → “2” button.



Close THI



Open THI

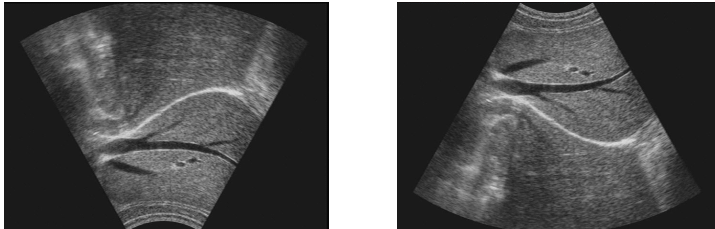
## 5.4 Image Flip

### Image polarity


Press “Image Processing” → “4” button continuously to change the image polarity.

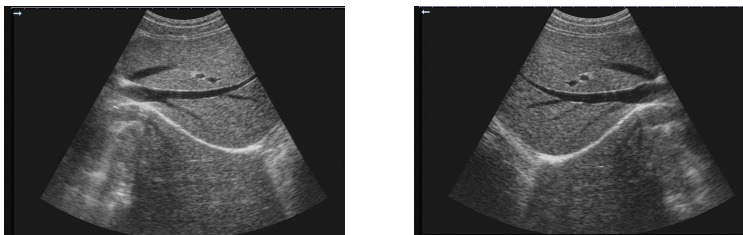
### Upside down

Press “U/D” continuously in non-4B mode to realize the upside down of image.



### Turning around

Press “L/R” continuously in real-time scanning state of B, BB, 4B mode to realize the turning around of image. The  which on top left of screen is the indicator of image scanning direction.



## 5.5 Gray correction

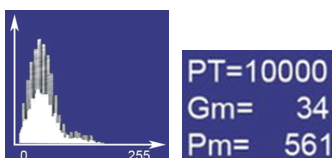
Press “Image Processing” → “5” button to active this function. The “GY” on the right of screen is lightening. Then adjust the gray scale of image with  $\uparrow \downarrow$  key. The adjustment range is GY0-GY7.

### Tip:

**When an external monitor is applied, the image might be properly displayed only by gray scale correction.**

## 5.6 Bar chart

Press “Image Processing” → “6” in turn to call out sample frame after the image is frozen. Move the frame to the interest image area, Adjust the size of the sample frame with  $\uparrow \downarrow$  key, press “Measure” to conduct measurement. Meanwhile the statistics coordinate and statistics result are displayed on the bottom right of screen.



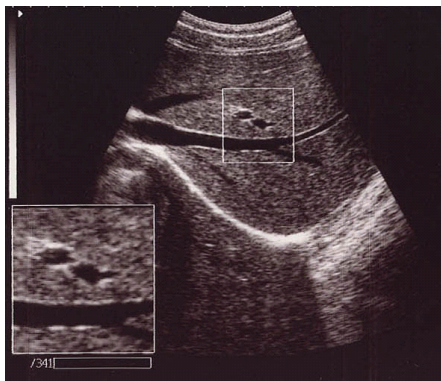
In the coordinates, X axis presents gray value and Y axis presents pixels number.

In the statistics result, PT presents pixels number of the sample frame, GM and PM present the corresponding gray value and pixels number of the highest point in the statistics chart.

Press “**Clear**” to exit the bar chart statistics.

## 5.7 Zoom

At real time or freeze state, press “Zoom” key to display or close sampling windows. Move “sampling window” by trackball. In order to change the sizes of windows, press  $\uparrow \downarrow$  keys.



## 6 Explanation

### 6.1 Overview

Press “Annotation” to display explanation menu which including image explanation functions, then press the corresponding number to enter. The “V1.12” at the top of menu presents current software version number. Press “Cancel” button to exit the menu.

-----V1.12-----  
1. NAME  
2. PID  
3. AGE  
4. SEX  
5. COMMENT  
6. TIME  
7. HOSP  
8. DOCT  
9. ERASE  
A. OBTABLE

### 6.2 Type the basic information of the patient and hospital

First press the "NEW-P" key to clear patient information , Type the basic information according to the following method.

#### NAME

Press “Annotation”→“1”in turn to display the following dialog box:

PLEASE ENTER NAME:  
■

15 characters maximum can be put in (letter, number or space), press “ ← ” to delete the input mistakes.

After input, press “Confirm” key to exit.

#### PATIENT ID

Press “Annotation”→“2” in turn to display the following dialog box:

PLEASE ENTER PID  
■

You can enter numbers and letters, input method with the "Name", enter up to 8 characters.

#### AGE

Press “Annotation”→“3” in turn to display the following dialog box:

PLEASE ENTER AGE:  
■

Age is composed by three numbers, and the input method is the same with the method which “NAME” adapts.

## **GENDER**

Press “Annotation”→“4” in turn to display the following dialog box:

PLEASE ENTER SEX:  
1.MALE      2.FEMALE

Press the corresponding number to select.

## **HOSPITAL**

Press “Annotation”→“7” in turn to display the following dialog box:

PLEASE ENTER HOSP:  
■

The input method is the same with the method which “NAME” adapts, and the maximum character number is 18.

## **DOCTOR**

Press “Annotation”→“8” in turn to display the following dialog box:

PLEASE ENTER DOCT:  
■

The input method is the same with the method which “NAME” adapts, and the maximum character number is 14.

## **6.3 Image explanation**

Press “Annotation”→“5” in turn into the image explanation function. The white cursor will display on the screen. Move the trackball cursor, you can annotate anywhere within the image area. At the same time the bottom of the screen will display the Chinese character’s shortcut key, press the corresponding number keys (0-9), the cursor will input the same characters.

When finishing the comment, press “Annotation” or “Cancel” key on the board to end this operation.

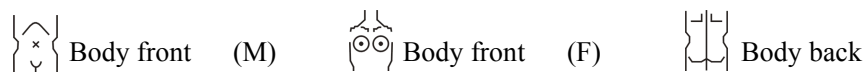
## **6.4 Body mark**

### **Body mark**

Press “**Body mark**” key to active body mark. There are 40 body marks, press this key repeatedly to display

these marks circularly

### 1. Abdomen



### 2. Obstetric



### 3. Head



### 4. Heart



### 5. Others



## Position indicator

When the Body mark shows, Press “**Confirm**” key to tune out Position indicator↖, Press “**Reference**” key to adjust directions, Then move it with trackball to make marks on the Body mark, Finally Press “**Cancel**” key to complete and exit.

Redo the above operation Can display more Position indicator.

## 6.5 date and clock adjustment

Press “Annotation”→“6” in turn to enter the date and clock adjustment dialog box:

YY-MM-DD  
HH-MM-SS

Type method: for example now is nine thirty-five thirty second on January 1st, 2010, then type 100101093530. Press “Confirm” to complete the typing and exit, the following box is listed as a reference.

YY-MM-DD  
100101  
HH-MM-SS  
093530



## **6.6 Screen cleaning**

press "Clear" key to clear the screen measurement mark and measurement results.

## 7 Image storage and Cine loop

### 7.1 Static image storage

The equipment offers storage space for 64 static images, and the date wouldn't be lost when the power-down.

Store image by the following steps:

1. First scan and freeze an image.
2. Press "**Save**" button in turn to save the image. The prompt "SAVING.....05" displayed on top left of screen indicates that the image saving is conducting, any other operation is forbidden. And the prompt will disappear when the saving is completed.
3. Press "freeze" button to back to the real-time scanning state.

The image memory can number the image (01-64) automatically. If 01-20 is used, it would save from 21 the next time. When the memory is full (save over 64 images), the following dialog box would display during the image saving.

STORAGE IS FULL. ERASE NO.01?

1. YES    2. NO

Prompt whether the image NO.01 should be overwritten, you may choose yes or not.

#### Tip:

**When the memory is full, you may export one image, and then conduct image saving. The system would prompt whether clear or save from the removed image number.**

### 7.2 Image export

1. Press "**Recall**" button in turn to display the following dialog box:

PLEASE ENTER STORAGE NO.:

■

2. Type the memory number (such as "01", press "←" to delete if there is wrong type.), then press "**Confirm**" to export the first saved image. On the bottom left of screen it displays 01/64 to present current image number and memory capacity. Now press "↑ ↓" to export other images in turn.
3. Press "**Freeze**" to back to real-time scanning mode, and repeat the above steps to export other images.

## 7.3 Image cleaning

Press “**Annotation**”→“9” in turn to display the following dialog box:

ERASE ALL STORAGE?  
1.YES 2.NO

Press “**1**” to confirm the image cleaning. The prompt “ERASING... ..”displayed on top left of screen indicates that the image cleaning is conducting, any other operation is forbidden. And the prompt will disappear when the cleaning is completed.

Press “**2**”to stop the image cleaning.

## 7.4 Cine loop

First of all, save all pieces of static image in temporary memory (the data in temporary memory will be lost when the power is off), then play these static image continuously to realize the function of cine loop.

Operate as the following steps:

1. Start the equipment into real-time scanning mode, and allow the equipment to conduct the cine loop image collection, the collect time is about 30 seconds.
2. Freeze the image, press “**Cine loop**” button in turn to playback, and the image is played in a continuous loop. The playback state “120/508 →”is displayed on the bottom left of the screen. “120/508” present current frame and total frame separately.
3. During the playback to realize frame step play with ↑ ↓ key or Trackball. Press “**Cine loop**” button in turn again to back to auto repeat mode.
4. Press “**Freeze**” button to exit the cine loop.

### Tip:

**Press “BB” button to switch different windows during the playback in BB mode.**

**If the image scanning way, probe or display mode is changed, the cine loop operation wouldn’t work until ordinary scanning is conducted for 30 seconds.**

**The cine loop time will be changed by the change of angle. The current playback information is displayed on the bottom left of the screen.**

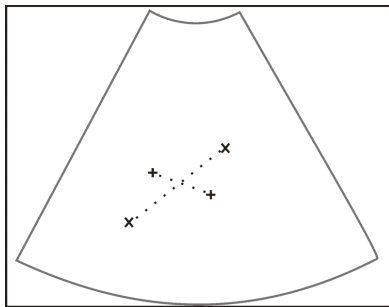
## 8 Measurement

### 8.1 Ordinary measurement

#### 8.1.1 Distance measurement

1. First freeze the image.
2. Press “DIST” to display the measurement cursor.
3. Move the cursor to measurement start point.
4. Press “Reference”, and move the cursor to measurement end point. (press “Reference” to switch the start and end cursor)
5. Press “Cancel” to end the measurement.

Repeat steps 2-5 to measure continuously. Up to 4 groups of measurement is allowed. If you want to continue the measurement after 4 groups, the original data would be overwritten. The current measure result would be displayed on the right of screen. The distance rate is listed as “D1/D2, D3/D4”. Press “Clear” to clear the measurement mark and measurement result.



Distance measurement chart

#### 8.1.2 perimeter/area measurement

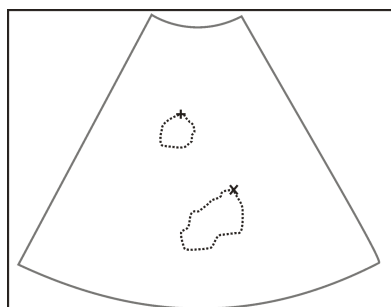
##### Free measurement

1. First clean the origin data on the screen.
2. Press “**A/C**” in turn to display following dialog box:

PLEASE ENTER:  
1.FREEHAND 2.ELLIPSE

3. Press “1” to choose free method, and the measure cursor is displayed on the screen.
4. Move the cursor to measurement start point.
5. Press “Reference”, move the cursor to end point through the edge of measure areas to form a closed path.
6. Press “Reference” to complete the measurement. If the curve is unclosed, the system would form a closed path automatically according to the shortest distance.

Press “**A/C**” key, Repeat steps 4-6 to measure continuously. Up to 2 groups of measurement is allowed. The result would be displayed on the right of screen. “C1/C2, A1/A2” are perimeter rate, area rate. Press “Clear” to re-measure.



Free measurement chart

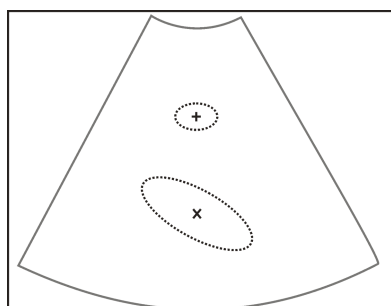
### Elliptical method measurement

1. First freeze the image.
2. Clean the origin date on the screen.
3. Press “**A/C**” in turn to display following dialog box:

PLEASE ENTER:  
1.FREEHAND 2.ELLIPSE

4. Press “2” to choose elliptical method, and the elliptical sample frame is displayed on the screen.
5. Move sample frame to measure area.
6. Press "Confirm", adjust the size by direction button.
7. Press "Reference" key, adjust the sample frame direction by trackball.
8. Press "Confirm", repeat steps 5-7 to re-adjust sample frame.
9. Press “Cancel” to end the measurement.

Press “**A/C**” key, Repeat steps 5-9 to measure continuously. Up to 2 groups of measurement is allowed. Press the middle button to end the measurement. The result would be displayed on the right of screen. Clear screen first if you want to re-measure.



Elliptical measurement chart

### 8.1.3 Volume measurement

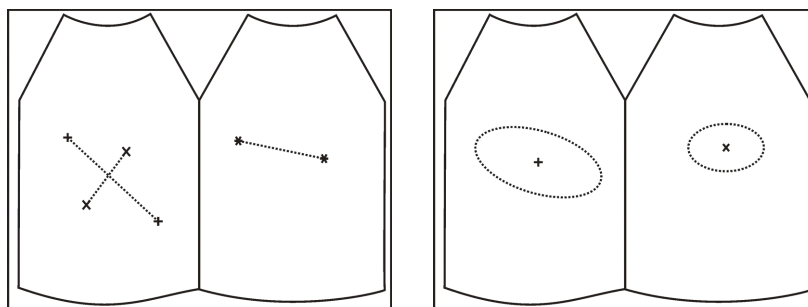
#### Triaxial method

1. Measure the distance of 3 groups or more according to distance measurement.
2. Press “Measure” or “Cancel” to display volume value.

“Vm1” on the right of screen indicates the current volume value.

### Elliptical method

Measure the perimeter/area value of two groups by elliptical method, the current volume value “Vm1” would be displayed on the right of screen.



Volume measurement chart

## 8.2 Cardiac Measurement

Obtain the satisfied image under the B/M or M mode and freeze. Press the “**Measure**” key and the cardiac measurement menu will appear, The “V1.12” at the top of menu presents current software version number.

Press “Cancel” button to exit the menu.

-----V1.12-----	
1. LV<VF>	
2. AV	
3. MV	
4. PV	
5. TV	
6. HR	

1. Left Ventricular
2. Aortic Valve
3. Mitral Valve
4. Pulmonary Valve
5. Tricuspid Valve
6. Heart Rate

### 8.2.1 Left Ventricular Measurement

By measuring the diastolic period and systolic period: posterior wall of the right ventricular, anterior wall of the interventricular septum, posterior wall of the interventricular septum, endocardium of the posterior wall of the left ventricular, epicardium; to calculate the diastolic period and systolic period respectively: thickness of the left cardiac wall, diameter of the right ventricular, diameter of the left ventricular, thickness of the posterior wall of the left ventricular, thickness of the interventricular septum, volume of the left ventricular, heartbeat flow, ECG output, systolic fraction and ejection fraction.

Operation Procedure:

1. Enter the B/M mode, and move the mouse to change the position of the sampling lime. Press the “Freeze” key when the proper M mode image appears;
2. Press the “**Measure**” key and the cardiac measurement menu will appear;
3. Press the “1” key to select “LV<VF>”, a vertical time bar will appear in the M image;
4. Move the time bar to the end of the diastolic period and press the “Confirm” key, mark the anterior wall of the right ventricular (D1) with Confirm key. Some mark points of the diastolic period are

described as follows and mark the following several points with the same method:

D2—Posterior Wall of the Right Ventricular in the Diastolic Period

D3—Anterior Wall of the Interventricular Septum in the Diastolic Period

D4—Posterior Wall of the Interventricular Septum in the Diastolic Period

D5—Endocardium of the Posterior Wall of the Left Ventricular in the Diastolic Period

D6—Epicardium in the Diastolic Period

5. (D6) After marking, the second time bar will appear, move the time bar to the end of the diastolic period and press “Confirm” key and mark the anterior wall of the right ventricular (S1) of the systolic period with “Confirm” key. Some mark points of the diastolic period are described as follows and mark the following several points with the same method:

S2—Posterior Wall of the Right Ventricular in the Systolic Period

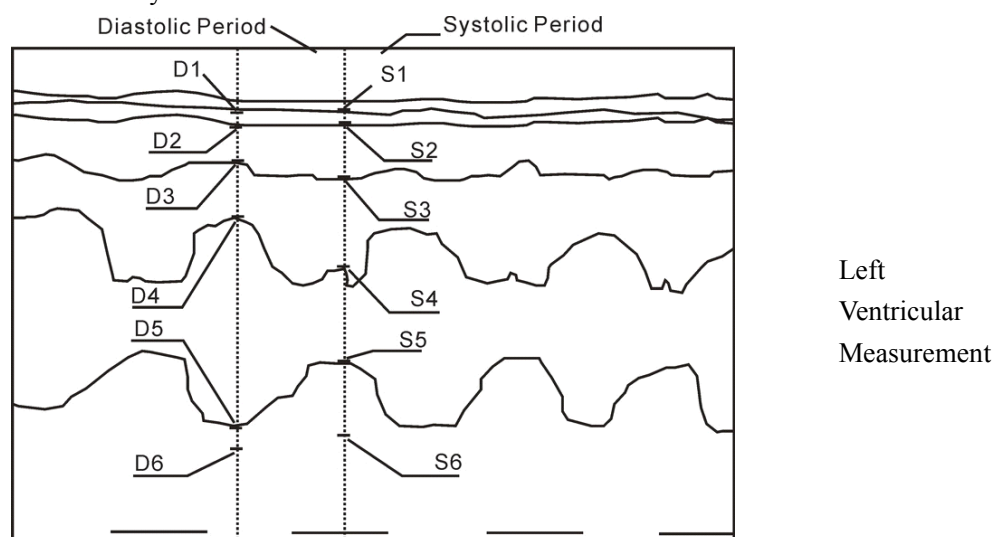
S3—Anterior Wall of the Interventricular Septum in the Systolic Period

S4—Posterior Wall of the Interventricular Septum in the Systolic Period

S5—Endocardium of the Posterior Wall of the Left Ventricular in the Systolic Period

S6—Epicardium in the Systolic Period

6. (S6) After the marking finishes, the measurement results will display on the right side of the screen automatically.



RHWD—Thickness of the Right Cardiac Wall in the Diastolic Period (mm)

RHWS—Thickness of the Right Cardiac Wall in the Systolic Period (mm)

RVD—Right Ventricular Diameter in the Diastolic Period (mm)

RVS—Right Ventricular Diameter in the Systolic Period (mm)

LVDD—Left Ventricular Diameter in the Diastolic Period (mm)

LVDS—Left Ventricular Diameter in the Systolic Period (mm)

PLVWD—Thickness of the Posterior Wall of the Left Ventricular in the Diastolic Period (mm)

PLVWS—Thickness of the Posterior Wall of the Left Ventricular in the Systolic Period (mm)

IVSD—Thickness of the Interventricular Septum in the Diastolic Period (mm)

IVSS—Thickness of the Interventricular Septum in the Systolic Period (mm)

LVEDV—Left Ventricular Volume at the end of the Diastolic Period (ml)

LVESV—Left Ventricular Volume at the end of the Systolic Period (ml)

SF—Systolic Fraction (%)

EF—Ejection Fraction (%)

SV—Heartbeat Volume (ml)

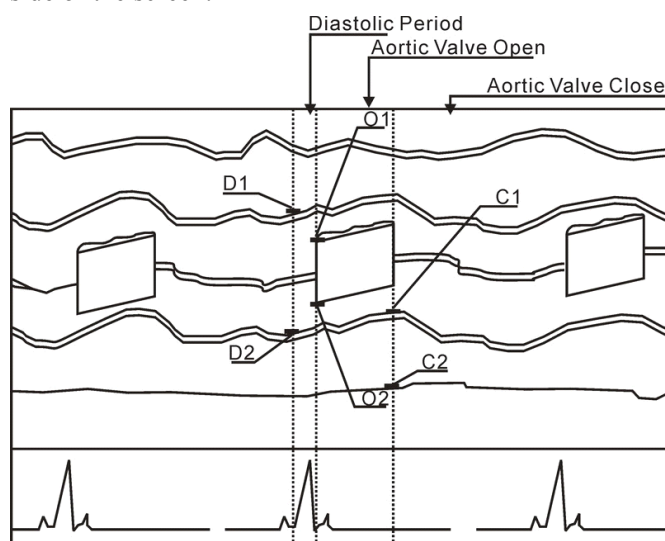
CO—ECG Output (ml)

## 8.2.2 Aortic Valve Measurement

Calculate the aortic valve diameter, open size of the aortic valve and the ratio between the aortic valve and left atrium to study the aortic valve.

Operation Procedure:

1. Enter the B/M mode and move the mouse to change the position of the sampling line. Press the “Freeze” key when proper M mode image appears;
2. Press the “Measure” key and the cardiac measurement menu will appear;
3. Press the “2” key to select “AV”, and a vertical time bar will appear in the M image;
4. Move the time bar to the end of the diastolic period and press “Confirm” key, mark the anterior wall of the aortic valve (D1) and the posterior wall of the aortic valve (D2) with “Confirm” key, the second time bar will appear after the marking;
5. Move the time bar to the open point of the aortic valve and press “Confirm” key, mark the anterior lobe of the aortic valve (O1) and posterior lobe of the aortic valve (O2) with the same method, the third time bar will appear after the marking;
6. Move the time bar to the close point of the aortic valve and press “Confirm” key, mark the posterior wall of the aortic valve (C1) and posterior lobe arterial wall (C2);
7. When all the measurements finish, the calculation results of the aortic valve will display on the right side of the screen.



Aortic Valve Measurement

AO—The Aortic Root Diameter at the end of the Diastolic Period (mm)

LA—Diameter of the Left Ventricular at the end of the Systolic Period (mm)

AVO—Distance between the Aortic Anterior Lobe and Posterior Lobe and the Open Point of the Aortic Valve (mm)

LAR—Left Atrium/Aorta Ratio

LVET—Left Ventricular Ejection Time (second)

## 8.2.3 Mitral Valve Measurement

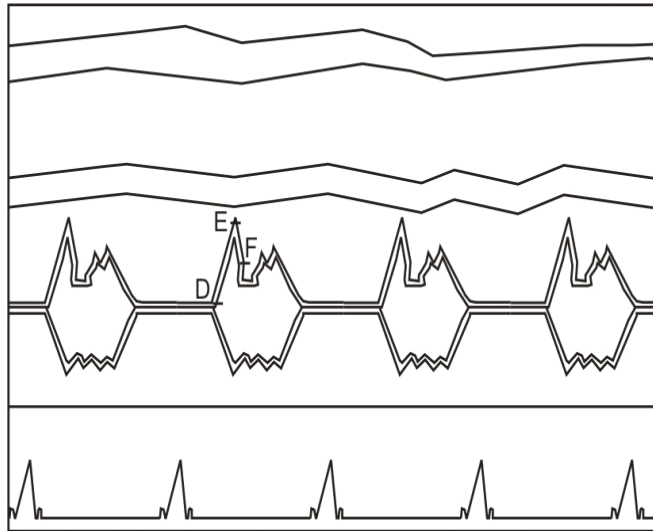
The research of the mitral valve allows the user to estimate the D-E and E-F displacement, D-E and E-F slope, D-E and E-F time on the D wave, E wave and F wave under the M mode and BM mode.

Operation Procedure:

1. Enter the B/M mode and move the mouse to change the position of the sampling line, press the “Freeze” key when the proper M mode image appears;



2. Press the “**Measure**” key and the cardiac measurement menu will appear;
3. Press the “3” key to select “MV”, move the cursor to the Q wave position of the M mode image area and press “Confirm” key, mark “D”;
4. Mark the following mitral valve waves with the same method;  
E: E Wave  
F: F Wave
5. After the marking finishes, the measurement results will display on the right side of the screen automatically.



Mitral Valve  
Measurement

DE<EX>—Distance from Point D to E on the Y Axis (mm)

EF<EX>—Distance from Point E to F on the Y Axis (mm)

DE<TM>—DE Time (second)

EF<TM>—EF Time (second)

DE<SL>—slope= (Point E on the Y Axis –Point D on the Y Axis)/ (Point F on the X Axis-Point D on the X Axis) (mm/second)

EF<SL>—slope= (Point E on the Y Axis –Point F on the Y Axis)/(Point F on the X Axis- Point E on the X Axis) (mm/second)

## 8.2.4 Pulmonary Valve Measurement

In this measurement, it is a characteristic calculation parameter. Calculate the pulmonary valve according to the following point marking position.

A: Maximum Downward Position of the Valve of the Atrial Systolic Period

B: Start Point of the Ventricular Systolic Period

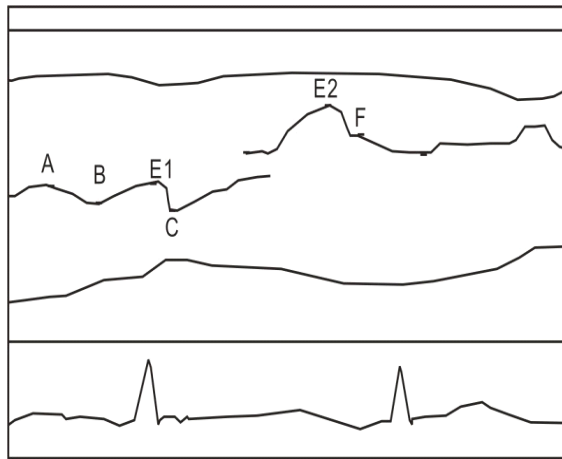
C: Maximum Open Point of the Lobule

E1: Start Point of the Ventricular Diastolic Period

E2: Complete Close Point of the Valve

F: Start Point of the Atrial Systolic Period

Mark the above points with the method described above, when the marking finishes, the measurement results will display on the right side of the screen automatically.



Pulmonary Valve  
Measurement

A<DEP>——Depth:

The distance from point F to point A is the distance from the start point of the atrial systolic period to the maximum downward position of the pulmonary valve. The distance from point F to A on the Y axis is the maximum movement range of the pulmonary valve in the atrial systolic period.

$A<DEP>Depth = AY - FY$  (mm)

AY is point A on the Y axis, and FY is point F on the Y axis.

EF<SL>——Slope:

When the initial blood flow from the atrium, E1 is the start point of the ventricular diastolic period and F is the inflow start point of the atrial systolic period.

$EF<SL>Slope = (FY - E1Y) / (FX - E1X)$  (mm/second)

FY is point F on the Y axis, E1Y is point E1 on the Y axis, FX is point F on the X axis and E1X is point E1 on the X axis.

BC<DS>——Diameter:

BC is the open part of the pulmonary valve in the ventricular systolic period and the part on the Y axis the movement distance of lobule when the pulmonary valve open to the maximum.

$BC<DS> diameter = CY - BY$  (mm)

CY is point C on the Y axis, and BY is point B on the Y axis.

BC<SL>——Slope:

$BC<SL>Slope = (CY - BY) / (CX - BX)$  (mm/second)

CY is point C on the Y axis, BY is point B on the Y axis, CX is point C on the X axis and BX is point B on the X axis.

RVET——Ejection Time of the Right Ventricular:

Ejection time of the right ventricular is the time from point B to E2 of the opening of the pulmonary valve.

$RVET = E2X - BX$  (second)

E2X is point E2 on the X axis, and BX is point B on the X axis.

## 8.2.5 Tricuspid Valve Measurement

Tricuspid valve measurement is similar to mitral valve measurement, and the following three points are used for:

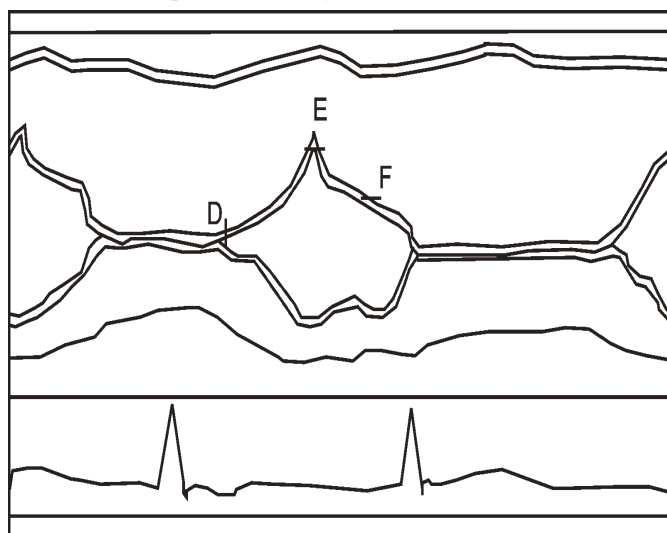
D: Open point of the tricuspid valve and the end of the systolic period of the right ventricular

E: Maximum Point of the Tricuspid Valve Orifice

F: The tricuspid valve closes completely

Mark the above points with the method described above, when the marking finishes, the measurement

results will display on the right side of the screen automatically.



Tricuspid Valve  
Measurement

DE<EX>— Distance from point D (right ventricular in the front of the tricuspid valve orifice) to point E (maximum tricuspid valve orifice) (mm)

EF<EX>—Distance from point E to point F on the Y axis (mm)

DE<TM>—DE time (second)

EF<TM>—EF time (second)

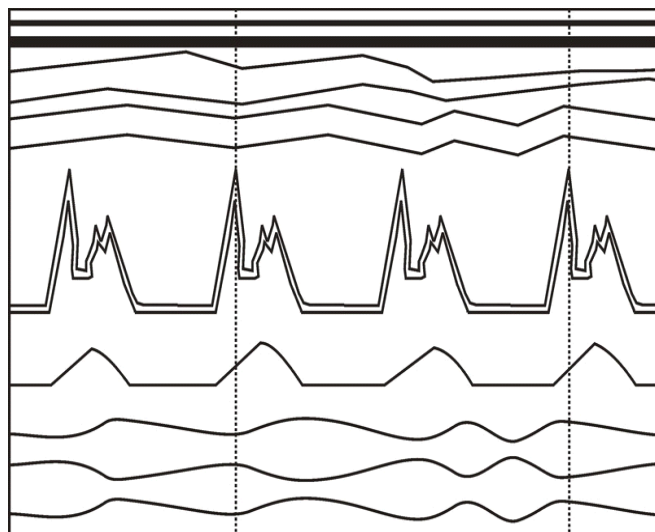
DE<SL>—Slope= (Point E on the Y axis–Point D on the Y axis)/ (Point F on the X axis – Point D on the X axis) (mm/second)

EF<SL>—Slope= (Point E on the Y axis–Point F on the Y axis) / (Point F on the X axis – Point E on the X axis) (mm/second)

## 8.2.6 Heart Rate Measurement

Operation Procedure:

1. Enter the B/M mode, move the mouse to change the position of the sampling line, press the “Freeze” key when proper M mode image appears;
2. Press the “**Measure**” key and the cardiac measurement menu will appear;
3. Press the “6” key to select “HR”, a vertical time bar appears in the M image;
4. Move the time bar to the first wave peak and press “Confirm” key, the second time bar appears;
5. Move the time bar to the third wave peak and press “Confirm” key;
6. The measurement finishes and the measurement results will display on the right side of the screen.



Heart Rate  
Measurement

TM—Time (second)

HR— Heart Rate (times/minute)

### 8.3 Obstetrics calculation

The equipment can calculate gestation age, expected date of delivery according to 7 parameters such as BPD, FL, AC, HC, CRL, GS, first day of the last menses. Therein, BPD can be used to calculate fetus weight.

At freeze state, Press “**OB table**” key to display obstetrics table menu and press “**Cancel**” button to exit the menu.

TOKYO	
1.	BPD-FW
2.	FL
3.	AC
4.	HC
5.	CRL
6.	AD
7.	GS
8.	LMP

For BPD, FL, CRL, AD and GS, Measure the distance according to distance measurement method, the corresponding obstetrical table data display on screen right.

For AC, HC, Measure as per Ellipse measurement method for circumference and area, the device will automatically calculate the related data and display them on screen right.

Select "7. LMP", a reminder displays

PLEASE ENTER LMP: MM—DD
■

This reminder ask to put in the first date of the pregnant woman's last menses in the date format MM-DD.

For example: May 11, put in 05-11. When the correct date is put, measuring result will displays at "EDD" on screen right in the format of YY-MM-DD, For example 07-02-21 means that the expected date of delivery is on February 21,2007.

#### Note

**In expected date of delivery calculation, the system date must be correct.**

**The default standard pregnancy period in the system is 40 weeks. In last menses method measuring, if the time interval between the input date and the system date exceeds 40 weeks, the inward date will not be accepted and need to be put in again.**

**Under the condition of item 1, if the inward date is bigger than the current system date, it will be regarded as the date of the last year.**

### Set Obstetrics formula

Press “Annotation” to select "A. OBTABLE ", The remind box is given bellow:

PLEASE ENTER OBTABLE: < TOKYO >  
1. TOKYO 2. HADLOCK

Table TOKYO is suitable for Asian, and Table HADLOCK is suitable for European.

### Tips:

**Head circle (HC)、 abdomen circle (AC) only have the Hadlock form, this equipment does Not provide the HC, AC form under the Tokyo formula**

## 9 Report

The equipment will store the patient information, diagnosis annotation, measurement result and hospital, data, time, doctor and some other information in the report page with the diagnosis. The abdominal, cardiac, obstetrics and urological reports will generate automatically according to different measurement items, and store the last measurement results.

When the corresponding measurement finishes, press “Freeze” → “R” key, The report menu will display:

**1.ABDOMEN    2.CARDIAC    3. OB    4. UROLOGY**

Enter the corresponding number key to enter the related report and press any key to exit this menu.

### Abdominal Report, Urological Report:

HOSP: 9999HHH		DOCT:		ABDOMEN
PID:				09-06-06
NAME:		AGE:	SEX:	02:04:49
H01=		H01=		
X02=		H01=2		
X03=		X02=		
X04=		X02=2		
D1/D2=	0%	C1/C2=	0%	
D3/D4=	0%	A1/A2=	0%	
Um1=		Um1=		
COMMENT:				

### Cardiac Report:

HOSP: 9999HHH		DOCT:		CARDIAC
PID:				09-06-06
NAME:		AGE:	SEX:	02:05:05
LUKUF>	AU	MU	PU	TU
:	:	:	:	:
RHD= mm	AO = mm	DE(EX)= mm	A(DEP)= mm	DE(EX)= mm
RHS= mm	LA = mm	EF(EX)= mm	BC(OS)= mm	EF(EX)= mm
RVD= mm	AVD = mm	DE(TD)= 00.0 S	EF(SL)= 000mm/S	DE(TD)= 00.0 S
RUS= mm	LAR = mm	EF(TD)= 00.0 S	BC(SL)= 000mm/S	EF(TD)= 00.0 S
LVD= mm	LVET= 00.0 S	DE(SL)= 000mm/S	RVET= 00.0 S	DE(SL)= 000mm/S
LVS= mm		EF(SL)= 000mm/S		EF(SL)= 000mm/S
PLVD= mm				
PLVS= mm				
IUSD= mm				
IUS= mm				
LVEDU= 000.0ml				
LVEDU= 000.0ml				
SF= %				
EF= %				
SU= 000.0ml		HR		
CO= 0ml		:		
		TH= 00.0 S		
		HR= B/M		
COMMENT:				

### Obstetrics Report:

HOSP: 9999HHH		DOCT:		08	
PID:		AGE:		09-06-06	
NAME:		SEX:		02:05:21	
1		2		3	
AUG		G-A:		EDD:	
FW:					
BPD:					
FL :					
AC :					
HC :					
CRL:					
GS :					
TOTAL-AVG :		PSW: 0		10-00-02	
FW(BPD-AC):					
RATIO:		HC/AC= 0%		FL/AC = 0%	
				FL/BPD= 0%	
COMMENT:					

Press “**R**” to exit the report.

#### **Tips:**

**You can press the “Annotation” key on the report interface and then annotate information in the annotation box, Press “Confirm” to exit.**

**In the obstetrics report 1, 2, 3 means that biparietal diameter (BPD), femur length (FL), Crown-rump length (CRL) and gestational sac (GS) can be measured at most for three times, and AVG is the average value of the three measurement results. TOTAL-AVG is the average value of the gestational age (GA) and expected date of delivery (EDD).**

**In the obstetrics report, fetal weight (BPD, AC) is calculated through the biparietal diameter (BPD) and abdominal circumference (AC), and when the measured BPD and AC are unequal to zero, fetal weight will display here automatically.**

#### **Clear the contents of the report**

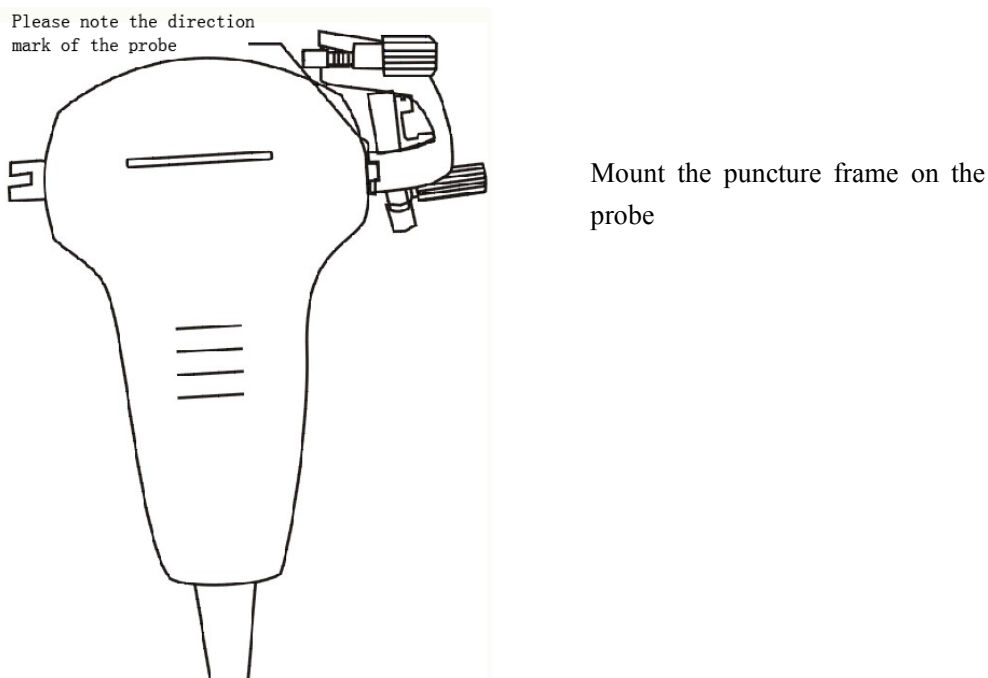
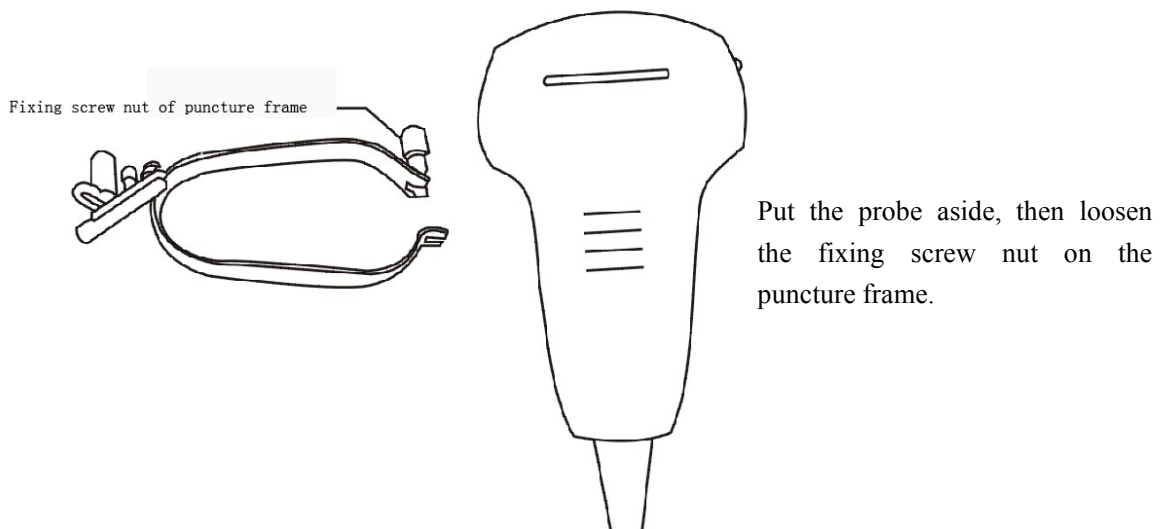
At real time or freeze, press “NEW-P” key to clear notation and report information on the image or the characters area.

## 10 Operating Instruction for Function of Puncture Guide

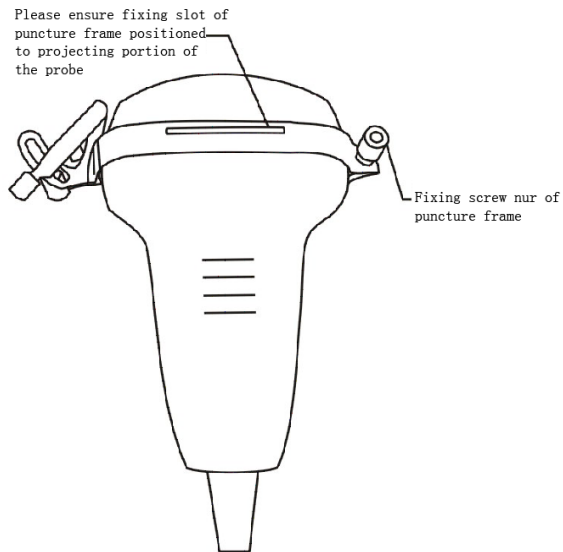
### Warning:

The puncture guiding line must be calibrated before performing a new puncture .If the puncture needle is not consistent with the puncture guiding line , please do not perform the puncture operation.

It is with risk when performing the puncture guided under ultrasound, thus it should be operated by operators with the proper qualification and capability ,and the preparative work before operation such as examination of clotting time ,BPC,electrocardiogram, blood pressure, sterilization of puncture set and puncture probe and signing of operation agreement should be done strictly.



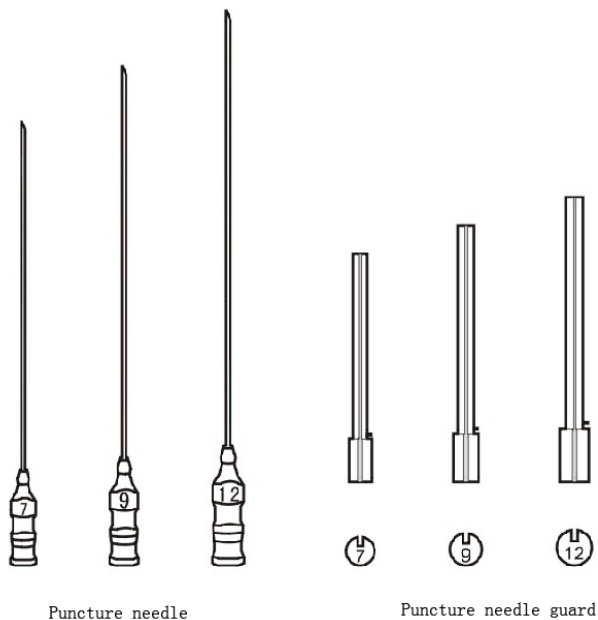




Buckle on the puncture frame and turn over the probe , then fasten the fixing screw nut of the puncture frame

## 10.2 Selection of Puncture Needles

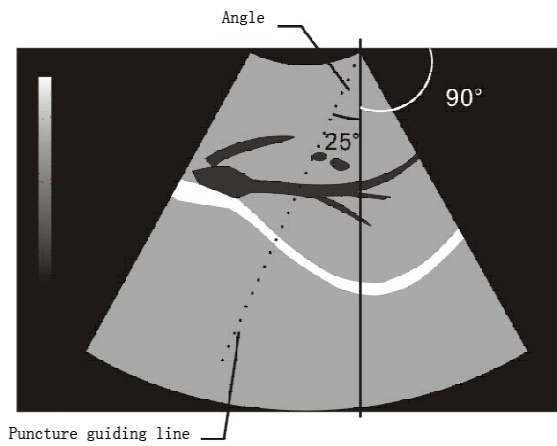
The puncture needles can be divided into 3 specification numbers such as No.7, No.9 and No.12. You can choose the proper puncture needle and needle guard based on the practical need. Please ensure that the specification number of selected puncture needle should be consistent with the selected needle guard.



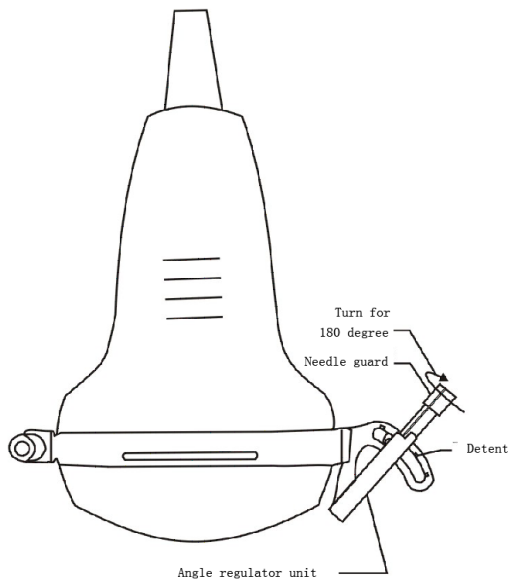
## 10.3 Call out the Puncture Guiding Line

Under the real time estate (single B mode), press “P” key, the screen will display the PT Sampling line, it calls puncture lead line, Press “1, 4” keys move to confirm the position, if want to exit, please press

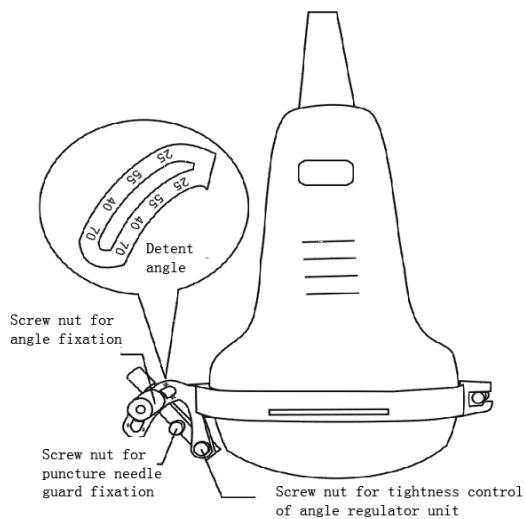
“Cancel” or “Clear” key.



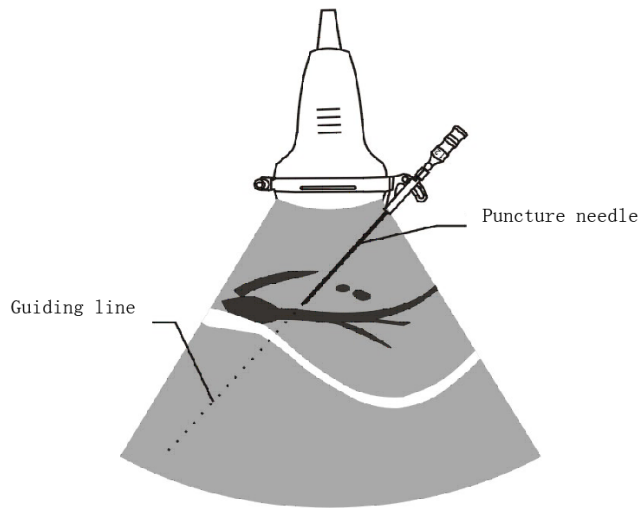
#### 4.4 Collection of Puncture Line



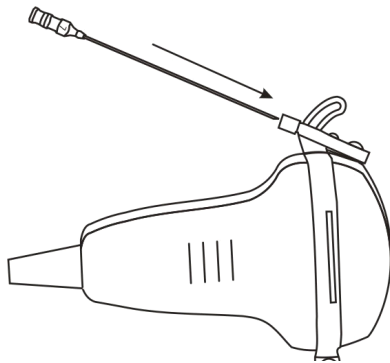
Fix the selected puncture needle on the angle regulator unit, then turn the puncture needle guard in ward for 180 degree. Thus the puncture angle can be adjusted by the angle regulator unit on the puncture frame



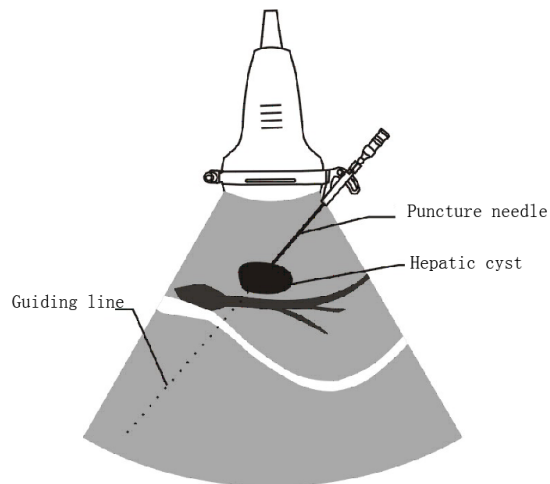
Please ensure that each type of angle should be identical with the detent (Detent Angle: 25°, 40°, 55°, 70°). The puncture needle angle should also be identical with the angle of puncture guiding line



## 10.5 Insertion of Puncture Needle

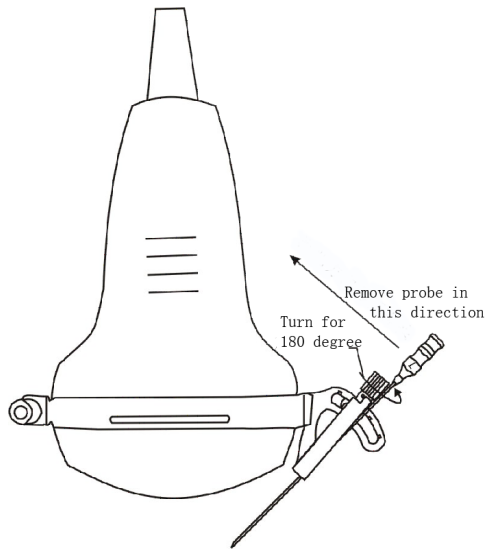


Please ensure that the tissue for puncture is on the puncture guiding line first. Then adjust the angle and insert the puncture needle slowly in the direction of needle guard



Please do not move the probe when inserting the puncture needle for ensuring the accuracy of the puncture operation

## 10.6 After Puncture



Turn the puncture needle guard outward for 180 degree to make the rabbet of the puncture needle guard outward, then remove the probe from it

Press “Cancel” or “Clear” key to exit the puncture guiding line

# 11 Check and Maintenance

## 11.1 Service life

Bases on the manufacturer's design, production related files, this model's use life is six years. The Product's material will gradually aging, if the product continually use over the designed use life, it may bring the problem of the performance reduced and fault rate raise.

### **Note:**

**The Discard the device according to local law.**

**Do not discard it mixing with other household garbage.**

### **Warning:**

**The manufacturer shall not assume the responsibility of risks caused by using the device beyond its service life.**

## 11.2 Main unit maintenance

- Instrumentation environment should accord with "Operation environmental requirement".
- If device enclosure needs cleaning, shutdown the device first and then wipe with alcohol sponges.
- Device should not turn on and off frequently.
- When the device does not work for a long time, pack the device according to the instructions on the packing. Store it properly in the warehouse. The storage environment should accord with "Transportation and storage environmental requirements".

### **Caution:**

**Please refer to instructions prescribed by the manufacturer closely when using detergents.**

**Be careful with cleaning of the display, because it is very easy to scratch and spoil.**

**Please wipe it with dry soft cloth.**

**Please do not clean the inner base of the device.**

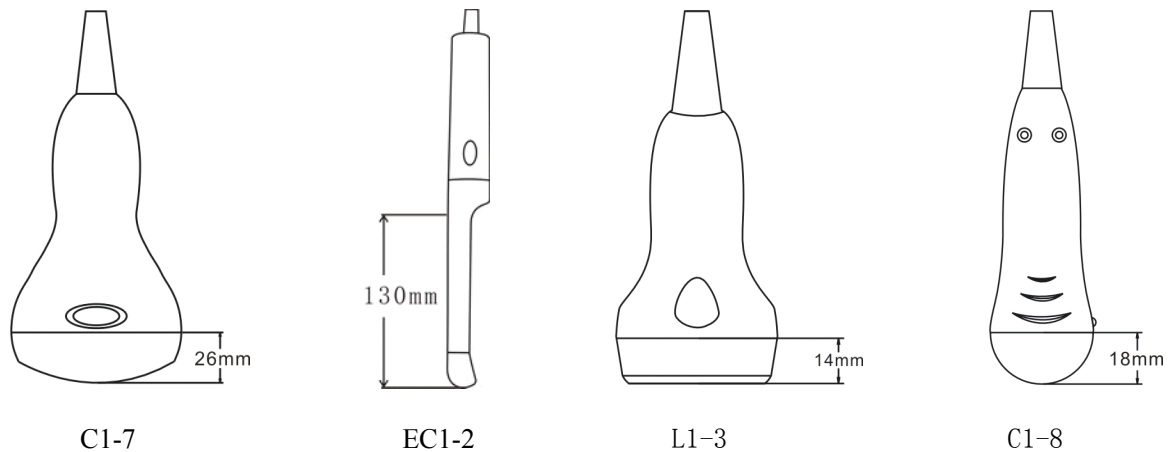
**Please do not place the device in liquid.**

**Do not leave any detergent on the device surface.**

**Though there will be no chemical reaction between the device enclosure and most of those detergents, We still suggest no detergent in cleaning lest the device surface is spoiled.**

### 11.3 Probe maintenance

- Probe is an expensive and frangible part. Never hit it or drop it on floor. When diagnoses pauses, put the probe in its case and press “**Freeze**” key to keep it in a state of "Frozen".
- See to use medical ultrasound coupling gel during diagnosis. Degree of protection against harmful ingress of water is IPX7. For the probes, water should not immerge over the probe acoustic window (refer to figure). Regularly check the probe enclosure to ensure it is good incase liquid ingression spoil the inner components.



- Probe and host machine once tie , be request not to take down at will , for fear probe pin and socket's contract badness.

#### **Note:**

**Probe might be damaged due to long time covered coupling gel.**

**Clean the probe head after every use.**

**Do not clean the probe with a surgical brash neither soft brash. Only soft cloth can be used to clean it.**

**Do not press the probe on the patient too long to avoid discomfort.**

#### **Warning:**

**Must not use extender, ethylene oxide or any other organic solvent which tend to deface the probe's protective foil.**

**Must not place the probe in liquid or detergent.**

**Must keep the equipment or probe from any type of liquid's infiltration.**

**Must not clean device or probe by airing or heating.**

## **11.4 Correct usage of probe**

In order to prolong probe's service life and obtain optimum performance, follow these instructions:

1. Periodic inspection on probe cable, socket and acoustic window.
2. Shutdown the device first and then connect or disconnect the probe.
3. Do not drop probe or flint body, and never hit the probe acoustic window, otherwise probe should be damaged.
4. Never heat the probe.
5. Never bend or pull probe cable, otherwise the internal connection should be broken.
6. Use couplant only on probe header and then clean probe.
7. Inspect probe acoustical window, enclosure and cable seriously after probe cleaning. Never use the probe again if any crack or breakage is found.

## 12 Simple Trouble Shooting

### 12.1 Check

- Check if the power supply is ok or not, main unit power cable is connected well or not. When the supply voltage surpasses the equipment specified voltage range (a.c.110V $\sim$ 130V/220V $\sim$ 240V, 50Hz/60Hz), must not switch on the equipment.
- Check if the probe and main unit are connected well or not.
- Check power cable and probe lines regularly and replace the damaged or broken one if found.

### 12.2 Simple trouble shooting

No.	Malfunction phenomena	Troubleshooting
1	Open power switch of the device, with no signal appeared on the screen and the indicator light is not on.	1. Examine power supply; 2. Examine supply line and plug; 3. Examine whether the fuse is burned-out; 4. Examine the lightness adjusting knob of the monitor.
2	Discontinuous striae and snow appear on the screen.	1. Examine power supply: strike fire interfere of the other devices; 2. Environmental examination: Electric and magnetic field interfere; 3. Examine power and probe plugs: whether they are well connected.
3	Unclear image display	1. Adjust the brightness and contrast knobs on the front panel; 2. Adjust the 8 level TGC and the total gain knob on the front panel; 3. Clean the screen optical filter.
4	Unclear near field	1. Adjust the total gain knob on the front panel and the 8 level TGC; 2. Adjust the focus position to the near field;
5	Unclear far field	1. Adjust the total gain knob on the front panel and the 8 level TGC; 2. Adjust the focus number, space and position to set the focus in the far field.



## **13 Transportation and Storage**

### **13.1 Environment requirements on transportation and storage**

Environment temperature range:  $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$

Relative humidity range:  $<80\%$  ( $20^{\circ}\text{C}$ )

### **13.2 Transportation**

Signs on the packing box conform to 《Iconograph and sign of packing, storage and transportation》 (GB/T191-2008) . Simple shockproof establishment is fitted within the box, which apply to aviation, railway, highway or steamship transportation. Keep dry, avoid inversion and collision.

### **13.3 Storage**

Equipment should be taken out from the packing when storage time exceeds six months, power on it for four hours, and then pack it correctly and keep it in a warehouse. The device must not be piled, and do not place it closely against the floor, walls or roof.

Keep it well ventilated, do not expose it to strong sunlight or caustic gases.

## Appendix A Acoustic output reporting table

**B mode**

**Nominal frequency: 3.5MHz**

**Trans ducer Model: C1-7/60R/3.5MHz**

**Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.**

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum index value			0.85	0.98	-	-	-	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.46					
	P (mW)			115.2	-		-	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zp<sub>ta</sub>,α</sub> Z <sub>s</sub> ]] (mW)					-		
	Z <sub>s</sub> (cm)					-		
	Z <sub>bp</sub> (cm)					-		
	Z <sub>b</sub> (cm)					-		
	Z at max. I <sub>pi,α</sub> (cm)		5.30					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						-	
	f <sub>awf</sub> (MHz)		2.91	2.91	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		1.64	-	-	-	#
Y (cm)			1.30	-	-	-	#	
Other information	t <sub>d</sub> (μsec)		0.52					
	p <sub>rr</sub> (Hz)		3787					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		2.48					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						-	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		207.9					
Operating control conditions	F-PIN		1	1	-	-	-	#
	Power,%		80	80	-	-	-	#
	Angle,°		30	30				
	Focus position		7	7				

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;

## Acoustic output reporting table

**M mode(Inc B mode)**

**Nominal frequency: 3.5MHz**

**Transducer Model: C1-7/60R/3.5MHz**

**Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.**

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum index value			0.89	0.49	-	0.036-	0.11	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.51					
	P (mW)			82.0	-		4.7	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zpta,α</sub> Z <sub>s</sub> ] (mW)					2.61		
	Z <sub>s</sub> (cm)					2.94		
	Z <sub>bp</sub> (cm)					2.94		
	Z <sub>b</sub> (cm)						5.07	
	Z at max. I <sub>pi,α</sub> (cm)		5.30					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						0.35	
	f <sub>awf</sub> (MHz)		2.91	2.91	-	2.90	2.90	#
	Dim of A <sub>aprt</sub>	X (cm)		2.35	-	2.34	2.34	#
		Y (cm)		1.30	-	1.30	1.30	#
Other information	t <sub>d</sub> (μsec)		0.53					
	p <sub>rr</sub> (Hz)		4166					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		2.58					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						0.34	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		203.9					
Operating control conditions	F-PIN		1	1	-	1	1	#
	Power,%		80%	80%	-	80%	80%	#
	Angle,°		30	30		30	30	#
	Focus position		7	7	-	7	7	#
	M Speed,S		1.25	1.25	-	1.25	1.25	#

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;

## Acoustic output reporting table

**B mode**

**Nominal frequency: 5.0MHz**

**Transducer Model: C1-8/20R/5.0MHz**

**Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.**

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum Index value			0.64	0.19	-	-	-	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.26					
	P (mW)			10.0	-		-	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zp<sub>ta,α</sub></sub> Z <sub>s</sub> ]] (mW)					-		
	Z <sub>s</sub> (cm)					-		
	Z <sub>bp</sub> (cm)					-		
	Z <sub>b</sub> (cm)					-		
	Z at max. I <sub>pi,α</sub> (cm)		2.98					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						-	
	f <sub>awf</sub> (MHz)		3.87	3.87	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		0.52	-	-	-	#
Y (cm)			0.79	-	-	-	#	
Other information	t <sub>d</sub> (μsec)		0.43					
	p <sub>rr</sub> (Hz)		4784					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		1.87					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						-	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		117.2					
Operating control conditions	F-PIN		1	1	-	-	-	#
	Power,%		80	80	-	-	-	#
	Angle,°		90	90				
	Focus position		6	6	-	-	-	#

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;

## Acoustic output reporting table

**M mode(Inc B mode)**

**Nominal frequency: 5.0MHz**

**Transducer Model: C1-8/20R/5.0MHz**

**Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.**

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum index value			0.66	0.22	0.025	-	0.05	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.29					
	P (mW)			11.6	1.35		1.35	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zpta,α</sub> Z <sub>s</sub> ] (mW)					-		
	Z <sub>s</sub> (cm)					-		
	Z <sub>bp</sub> (cm)					-		
	Z <sub>b</sub> (cm)						2.68	
	Z at max. I <sub>pi,α</sub> (cm)		3.00					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						0.31	
	f <sub>awf</sub> (MHz)		3.86	3.86	3.88	-	3.88	#
	Dim of A <sub>aprt</sub>	X (cm)		0.63	0.63	-	0.63	#
		Y (cm)		0.79	0.80	-	0.80	#
Other information	t <sub>d</sub> (μsec)		0.43					
	p <sub>rr</sub> (Hz)		4807					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		1.93					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						0.30	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		119.1					
Operating control conditions	F-PIN		1	1	1	-	1	#
	Power,%		80%	80%	80%	-	80%	#
	Angle,°		90	90	90	-	90	#
	Focus position		6	6	6	-	6	#
	M Speed,S		1.25	1.25	1.25	-	1.25	#

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;

## Acoustic output reporting table

**B mode**

**Nominal frequency: 7.5MHz**

**Transducer Model: L1-3/7.5MHz**

**Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.**

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum index value			0.54	0.64	-	-	-	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.30					
	P (mW)			24.0	-		-	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zpta,α</sub> Z <sub>s</sub> ] (mW)					-		
	Z <sub>s</sub> (cm)					-		
	Z <sub>bp</sub> (cm)					-		
	Z <sub>b</sub> (cm)						-	
	Z at max. I <sub>pi,α</sub> (cm)		4.9					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						-	-
	f <sub>awf</sub> (MHz)		5.70	5.70	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		1.02	-	-	-	#
Y (cm)			0.71	-	-	-	#	
Other information	t <sub>d</sub> (μsec)		0.28					
	p <sub>rr</sub> (Hz)		5649					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		3.41					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						-	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		109.6					
Operating control conditions	F-PIN		1	1	-	-	-	#
	Power,%		80%	80%	-	-	-	#
	Focus position		3	3	-	-	-	#

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;

## Acoustic output reporting table

M-mode(Inc B mode)

Nominal frequency: 7.5MHz

Transducer Model: L1-3/7.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum Index value			0.56	0.60	0.029	-	0.045	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.34					
	P (mW)			22.1	1.06		1.06	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zpta,α</sub> Z <sub>s</sub> ] (mW)					-		
	Z <sub>s</sub> (cm)					-		
	Z <sub>bp</sub> (cm)					-		
	Z <sub>b</sub> (cm)						2.47	
	Z at max. I <sub>pi,α</sub> (cm)		4.90					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						0.20	
	f <sub>awf</sub> (MHz)		5.70	5.70	5.70	-	5.70	#
	Dim of A <sub>aprt</sub>	X (cm)		1.01	1.00	-	1.00	#
Y (cm)			0.70	0.70	-	0.70	#	
Other information	t <sub>d</sub> (μsec)		0.28					
	p <sub>rr</sub> (Hz)		5681					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		3.52					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						0.19	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		109.7					
Operating control conditions	F-PIN		1	1	1	-	1	#
	Power,%		80%	80%	80%	-	80%	#
	Focus position		3	3	3	-	3	#
	M Speed,S		1.25	1.25	1.25	-	1.25	#

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;

## Acoustic output reporting table

**B mode**

**Nominal frequency: 6.5MHz**

**Transducer Model: EC1-2/13R/6.5MHz**

**Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.**

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum Index value			0.64	0.23	-	-	-	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.38					
	P (mW)			10.0	-		-	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zpta,α</sub> Z <sub>s</sub> ] (mW)					-		
	Z <sub>s</sub> (cm)					-		
	Z <sub>bp</sub> (cm)					-		
	Z <sub>b</sub> (cm)					-		
	Z at max. I <sub>pi,α</sub> (cm)		2.48					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						-	
	f <sub>awf</sub> (MHz)		4.66	4.66	-	-	-	#
	Dim of A <sub>aprt</sub>	X (cm)		0.63	-	-	-	#
Y (cm)			0.79	-	-	-	#	
Other information	t <sub>d</sub> (μsec)		0.31					
	p <sub>rr</sub> (Hz)		4807					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		2.05					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						-	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		120.1					
Operating control conditions	F-PIN		1	1	-	-	-	#
	Power,%		80	80	-	-	-	#
	Angle,°		120	120				
	Focus position		3	3	-	-	-	#

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;



## Acoustic output reporting table

M-mode(Inc B mode)

Nominal frequency: 6.5MHz

Transducer Model: EC1-2/13R/6.5MHz

Manufactured By: SHENZHEN WELL.D MEDICAL ELECTRONIC CO.,LTD.

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A <sub>aprt</sub> ≤1cm <sup>2</sup>	A <sub>aprt</sub> >1cm <sup>2</sup>		
Maximum index value			0.65	0.23	0.014	-	0.026	(a)
Associated acoustic parameters	P <sub>ra</sub> (MPa)		1.41					
	P (mW)			10.2	0.62		0.62	#
	Min.of [P <sub>α</sub> (Z <sub>s</sub> ), I <sub>zpta,α</sub> Z <sub>s</sub> ] (mW)					-		
	Z <sub>s</sub> (cm)					-		
	Z <sub>bp</sub> (cm)					-		
	Z <sub>b</sub> (cm)						2.36	
	Z at max. I <sub>pi,α</sub> (cm)		2.34					
	d <sub>eq</sub> (Z <sub>b</sub> ) (cm)						0.26	
	f <sub>awf</sub> (MHz)		4.66	4.66	4.61	-	4.61	#
	Dim of A <sub>aprt</sub>	X (cm)		0.62	0.62	-	0.62	#
Y (cm)			0.80	0.79	-	0.79	#	
Other information	t <sub>d</sub> (μsec)		0.31					
	p <sub>rr</sub> (Hz)		4807					
	p <sub>r</sub> at max. I <sub>pi</sub> (MPa)		2.05					
	d <sub>eq</sub> at max. I <sub>pi</sub> (cm)						0.25	
	I <sub>pa,α</sub> at max. MI (W/cm <sup>2</sup> )		124.1					
Operating control conditions	F-PIN		1	1	1	-	1	#
	Power,%		80%	80%	80%	-	80%	#
	Angle,°		120	120	120	-	120	#
	Focus position		3	3	3	-	3	#
	M Speed,S		1.25	1.25	1.25	-	1.25	#

### Notes:

(a) This probe is not intended for transcranial or neonatal cephalic use;

## Appendix B Obstetrics

### Head circumference (HC)

Table Set1: Hadlock,F.P.,et al.Method

HC	WEEKS	S. D		HC	WEEKS	S. D
mm	w. d.	± days		mm	w. d.	± days
56	12. 0	8		210	23. 1	11
63	12. 3	8		217	23. 5	11
70	12. 6	8		224	24. 3	15
77	13. 2	8		231	25. 1	15
84	13. 5	8		238	25. 6	15
91	14. 1	8		245	26. 4	15
98	14. 4	8		252	27. 3	15
105	15. 0	8		259	28. 1	15
112	15. 3	8		266	29. 0	15
119	15. 6	8		273	29. 6	15
126	16. 3	8		280	30. 5	21
133	16. 6	8		287	31. 4	21
140	17. 2	8		294	32. 4	21
147	17. 6	8		301	33. 3	21
154	18. 3	11		308	34. 3	21
161	18. 6	11		315	35. 2	19
168	19. 4	11		322	36. 3	19
175	20. 0	11		329	37. 3	19
182	20. 4	11		336	38. 4	19
189	21. 1	11		343	39. 4	19
196	21. 6	11		350	40. 5	19
203	22. 3	11				

## Femur length (FL)

Table Set1: Tokyo University Method

FL	WEEKS	S. D		FL	WEEKS	S. D
mm	w. d.	$\pm$ days		mm	w. d.	$\pm$ days
8	12. 3	10		42	24. 5	24
10	13. 0	10		44	25. 2	25
12	13. 4	10		46	26. 0	25
14	14. 1	10		48	27. 0	25
16	14. 5	10		50	28. 0	25
18	15. 2	10		52	29. 0	30
20	16. 0	10		54	29. 5	30
22	16. 4	10		56	30. 2	30
24	17. 1	10		58	31. 3	32
26	17. 6	10		60	33. 0	38
28	18. 4	14		62	34. 0	42
30	19. 2	17		64	35. 0	46
32	20. 5	17		66	36. 5	50
34	21. 5	18		68	38. 0	57
36	22. 3	19		70	40. 0	64
38	23. 0	21		72	40. 2	64
40	24. 0	22				

## Femur length (FL)

Table Set2: Hadlock, F. P. ,et al. Method

FL	WEEKS	S. D		FL	WEEKS	S. D
mm	w. d.	$\pm$ days		mm	w. d.	$\pm$ days
8	12. 3	10		46	25. 2	15
10	13. 0	10		48	26. 1	15
12	13. 4	10		50	26. 6	15
14	14. 1	10		52	27. 5	15
16	14. 5	10		54	28. 4	15
18	15. 2	10		56	29. 4	15
20	16. 0	10		58	30. 2	21
22	16. 4	10		60	31. 1	21
24	17. 1	10		62	32. 1	21
26	17. 6	10		64	33. 1	21
28	18. 4	14		66	34. 0	21
30	19. 2	14		68	34. 6	21
32	20. 0	14		70	35. 6	21
34	20. 5	14		72	36. 6	22
36	21. 3	14		74	37. 6	22
38	22. 1	14		76	38. 6	22
40	22. 6	14		78	39. 6	22
42	23. 5	14		80	40. 6	22
44	24. 4	15		82	42. 0	22

## Crown-rump length (CRL)

Table Set1: Tokyo University Method

CRL	WEEKS	S. D		CRL	WEEKS	S. D
mm	w. d.	± days		mm	w. d.	± days
6	6. 3	7		54	12. 4	7
8	6. 6	7		56	12. 5	7
10	7. 1	7		58	13. 0	7
12	7. 4	7		60	13. 1	7
14	7. 6	7		62	13. 2	7
16	8. 1	7		64	13. 3	7
18	8. 4	7		66	13. 4	7
20	9. 1	7		68	13. 5	7
22	9. 2	7		70	13. 6	7
24	9. 4	7		72	14. 0	8
26	9. 6	7		74	14. 1	8
28	10. 2	7		76	14. 2	8
30	10. 3	7		78	14. 3	8
32	10. 4	7		80	14. 4	8
34	10. 6	7		82	14. 5	8
36	11. 0	7		84	14. 6	8
38	11. 1	7		86	15. 0	8
40	11. 3	7		88	15. 1	14
42	11. 4	7		90	15. 2	14
44	11. 6	7		92	15. 3	14
46	12. 0	7		94	15. 4	14
48	12. 1	7		96	15. 5	14
50	12. 2	7		98	15. 6	14
52	12. 3	7		100	16. 0	14

## Crown-rump length (CRL)

Table Set2: Hadlock,F.P.,et al.Method

CRL	WEEKS	S. D		CRL	WEEKS	S. D
mm	w. d.	± days		mm	w. d.	± days
4	6. 1	3		68	13. 1	6
6	6. 3	3		70	13. 1	6
8	6. 5	3		72	13. 3	6
10	7. 1	3		74	13. 3	6
12	7. 3	3		76	13. 5	6
14	7. 5	3		78	13. 6	6
16	8. 0	3		80	14. 0	6
18	8. 2	3		82	14. 1	6
20	8. 4	4		84	14. 2	6
22	8. 6	4		86	14. 3	6
24	9. 1	4		88	14. 5	6
26	9. 3	4		90	14. 6	6
28	9. 4	4		92	15. 1	6
30	9. 6	4		94	15. 2	6
32	10. 1	5		96	15. 3	6
34	10. 2	5		98	15. 4	6
36	10. 4	5		100	15. 6	6
38	10. 5	5		102	16. 1	6
40	10. 6	5		104	16. 2	6
42	11. 1	5		106	16. 3	7
44	11. 1	5		108	16. 5	7
46	11. 3	5		110	16. 6	7
48	11. 4	6		112	17. 1	7
50	11. 5	6		114	17. 2	7
52	11. 6	6		116	17. 3	7
54	12. 0	6		118	17. 5	7
56	12. 1	6		120	17. 6	7
58	12. 2	6				
60	12. 3	6				
62	12. 4	6				
64	12. 6	6				
66	12. 6	6				

## Gestational Sac (GS)

Table Set1: Tokyo University Method

GS	WEEKS	S. D		GS	WEEKS	S. D
mm	w. d.	$\pm$ days		mm	w. d.	$\pm$ days
10	4. 0	7		42	9. 1	14
12	4. 1	7		44	9. 3	14
14	4. 4	7		46	9. 4	14
16	5. 0	8		48	10. 0	15
18	5. 1	8		50	10. 1	15
20	5. 4	8		52	10. 3	15
22	6. 0	11		54	10. 4	15
24	6. 1	11		56	10. 6	15
26	6. 6	12		58	11. 1	16
28	7. 1	12		60	11. 3	16
30	7. 3	12		62	11. 4	16
32	7. 4	12		64	11. 6	16
34	8. 0	13		66	11. 8	16
36	8. 1	13		68	12. 1	17
38	8. 3	13				
40	8. 6	13				

## Gestational Sac (GS)

Table Set2: Hadlock,F.P.,et al.Method

GS	WEEKS	S. D		GS	WEEKS	S. D
mm	w. d.	$\pm$ days		mm	w. d.	$\pm$ days
6	5.0					
8	6.0					
10	6.0					
12	6.2					
14	6.4					
16	7.0					
18	7.2					
20	7.2					
22	7.4					
24	7.4					
26	8.0					
28	8.2					
30	8.4					
32	8.4					
34	8.6					
36	9.0					
38	9.3					
40	9.3					
42	9.5					
44	10.0					
46	10.0					
48	10.2					
50	10.4					
52	11.0					
54	11.2					
56	11.6					
58	12.0					
60	12.4					
62	13.0					
64	13.0					



## Biparietal diameter (BPD)

Table Set1: Tokyo University Method

BPD	WEEKS	S. D		BPD	WEEKS	S. D
mm	w. d.	± days		mm	w. d.	± days
16	11. 3	7		56	23. 0	11
18	11. 6	7		58	23. 5	11
20	12. 0	7		60	24. 2	12
22	12. 4	7		62	25. 0	12
24	13. 0	7		64	25. 6	12
26	13. 6	7		66	26. 3	13
28	14. 2	7		68	27. 3	13
30	14. 6	7		70	28. 0	13
32	15. 2	7		72	29. 0	14
34	16. 0	8		74	29. 5	14
36	16. 3	8		76	30. 1	15
38	17. 0	8		78	31. 1	16
40	17. 5	8		80	32. 1	16
42	18. 2	9		82	33. 0	18
44	19. 0	9		84	34. 0	20
46	19. 5	10		86	35. 5	25
48	20. 2	10		88	37. 0	25
50	21. 0	10		90	39. 0	25
52	21. 4	10		92	42. 0	25
54	22. 2	10				

## Biparietal diameter (BPD)

Table Set2: Hadlock,F.P.,et al.Method

BPD	WEEKS	S. D		BPD	WEEKS	S. D
mm	w. d.	$\pm$ days		mm	w. d.	$\pm$ days
14	11. 6	7		60	24. 4	16
16	12. 2	9		62	25. 1	16
18	12. 6	9		64	25. 6	16
20	13. 1	9		66	26. 4	16
22	13. 4	9		68	27. 3	16
24	14. 1	9		70	28. 1	16
26	14. 4	9		72	28. 6	16
28	15. 0	9		74	29. 5	16
30	15. 4	9		76	30. 4	22
32	16. 0	9		78	31. 2	22
34	16. 4	9		80	32. 1	22
36	17. 0	9		82	33. 0	22
38	17. 4	9		84	33. 6	22
40	18. 1	14		86	34. 5	22
42	18. 5	14		88	35. 4	22
44	19. 2	14		90	36. 4	24
46	19. 6	14		92	37. 3	24
48	20. 4	14		94	38. 2	24
50	21. 1	14		96	39. 1	24
52	21. 6	14		98	40. 1	24
54	22. 3	14		100	41. 1	24
56	23. 1	14				
58	23. 6	14				

## Abdominal circumference (AC)

Table Set1: Hadlock,F.P.,et al.Method

AC	WEEKS	95% Conf.		AC	WEEKS	95% Conf.
mm	w. d.	Limits (d)		mm	w. d.	Limits (d)
100	15. 4	13. 7-17. 5		235	27. 5	25. 5-29. 9
105	16. 1	14. 2-18. 0		240	28. 1	26. 0-30. 4
110	16. 4	14. 6-18. 4		245	28. 5	26. 5-30. 9
115	16. 6	15. 0-18. 8		250	29. 1	27. 0-31. 4
120	17. 2	15. 4-19. 2		255	29. 5	27. 5-31. 9
125	17. 6	15. 9-19. 7		260	30. 1	27. 1-33. 1
130	18. 1	16. 2-20. 2		265	30. 4	27. 6-33. 6
135	18. 4	16. 6-20. 6		270	31. 1	28. 1-34. 1
140	19. 1	17. 1-21. 1		275	31. 4	28. 6-34. 6
145	19. 4	17. 5-21. 5		280	32. 1	29. 1-35. 1
150	20. 0	18. 0-22. 0		285	32. 4	29. 6-35. 6
155	20. 3	18. 4-22. 4		290	33. 1	30. 1-36. 1
160	20. 6	18. 8-22. 8		295	33. 4	30. 6-36. 6
165	21. 2	19. 3-23. 3		300	34. 1	31. 1-37. 1
170	21. 5	19. 7-23. 7		305	34. 4	31. 6-37. 6
175	22. 1	20. 2-24. 2		310	35. 1	32. 1-38. 1
180	22. 4	20. 6-24. 6		315	35. 4	32. 6-38. 6
185	23. 1	21. 1-25. 1		320	36. 1	33. 6-38. 6
190	23. 4	21. 6-25. 6		325	36. 4	34. 1-39. 1
195	24. 0	21. 8-26. 2		330	37. 1	34. 6-39. 6
200	24. 4	22. 3-26. 7		335	37. 4	35. 1-40. 1
205	24. 6	22. 7-27. 1		340	38. 0	35. 6-40. 6
210	25. 3	23. 2-27. 6		345	38. 5	36. 2-41. 2
215	25. 6	23. 7-28. 1		350	39. 1	36. 7-41. 7
220	26. 2	24. 1-28. 5		355	39. 5	37. 2-42. 2
225	26. 6	24. 6-29. 0				
230	27. 2	25. 1-29. 5				

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